SB372.MPhA.pdf
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Position: FAV

MPhA
MARYLAND PHARMACISTS ASSOCIATION

Date: February 27, 2023
To: The Honorable Melony Griffith, Chair
From: Aliyah N. Horton, CAE, Executive Director, MPhA, 240-688-7808
Cc: Members, Senate Finance Committee
Re: **FAVORABLE SB 372 –** Health Occupations - Pharmacists - Administration of Vaccines

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The Maryland Pharmacists Association (MPhA) urges a favorable report for **SB 372 – Health Occupations – Pharmacists – Administration of Vaccines.**

- SB 372 would codify the Third Amendment to the federal PREP Act into Maryland law, which authorized pharmacists to administer vaccinations to children aged three and older without a prescription and based on the Advisory Committee on Immunization Policies (ACIP) immunization schedule.
- This was done in recognition of pharmacy accessibility, history of safe administration of vaccinations in pharmacies and decreased vaccination rates among children during the COVID-19 pandemic. It has been in effect since August 2020.
- Failure to pass SB 372 will result in a decrease in expectation of healthcare access for Marylanders when the PREP Act expires.
- The PREP Act authorization improved access to vaccines since most families live near a pharmacy. MPhA recognizes that it is crucial for children to be routinely evaluated by their physicians.
- Unfortunately, 11 Maryland counties are health professional shortage areas (HPSA); another 12 have areas that are designated as HPSA.
- 40% of children in Maryland are without a "medical home." They do not have a consistent relationship with a healthcare provider for well child visits and checkups.
- SB 372 addresses broad public health concerns by providing more flexibility and opportunities for families to meet their medical needs and the **requirement of pharmacists to counsel on the importance of well-child visits and the need for patients to follow-up with a health care provider.**
- Pharmacists/pharmacies have clear protocols in place for patient screenings to ensure vaccinations are appropriate. These protocols and training support:
    - identification and assessment of patients who are in need of service
    - mitigation of medication side effects
    - avoidance of contraindications
    - administration of vaccinations
    - provision of emergency care, if required
- Maryland law requires practitioners to report all immunizations into the ImmuNet system, so all physicians and pharmacists have access to a patient's records to eliminate duplicate administrations.

MARYLAND PHARMACISTS ASSOCIATION - Founded in 1882, MPhA is the only state-wide professional society representing all practicing pharmacists, pharmacy technicians and student pharmacists in Maryland. Our mission is to strengthen the profession of pharmacy, advocate for all Maryland pharmacists and promote excellence in pharmacy practice.

A FAVORABLE report is also supported by the Maryland Pharmacy Coalition

Full members:

- Maryland Pharmacists Association
- American Society of Consultant Pharmacists - Maryland Chapter
- Maryland Pharmaceutical Society
- Maryland Society of Health System Pharmacists
- University of Maryland Baltimore School of Pharmacy Student Government Association
- University of Maryland Eastern Shore School of Pharmacy Student Government Association
- Notre Dame of Maryland University School of Pharmacy Student Government Association

Affiliate members:

- University of Maryland Baltimore School of Pharmacy
- University of Maryland Eastern Shore School of Pharmacy
- Notre Dame of Maryland University School of Pharmacy
- Maryland Association of Chain Drug Stores

MD SB_372_NCPA_fav.pdf
Uploaded by: Belawoe Akwakoku
Position: FAV

February 28, 2023

The Honorable Melony Griffith, Chairwoman
The Honorable Katherine Klausmeier, Vice-Chairwoman
Senate Finance Committee
Miller Senate Office Building
11 Bladen Street, Room 2 West Wing
Annapolis Maryland, MD 21401

RE: SENATE BILL 372 – PHARMACISTS – ADMINISTRATION OF VACCINES

Dear Chairwoman Griffith, Vice-Chair Griffith and committee members:

We thank you for the opportunity to submit testimony on **Senate Bill 372**, a bill that authorizes licensed pharmacists to independently order and administer vaccines to individuals 3 years and older. We **support** this bill as it ensures pharmacists will be able to continue administering vaccines after their temporary federal authority to administer expires.

NCPA represents the interest of America's community pharmacists, including owners of more than 19,400 independent community pharmacies across the United States and 332 independent pharmacies in Maryland. These Maryland pharmacies filled over 20 million prescriptions last year, impacting the lives of thousands of patients in your state.

With over 5,000 pharmacists practicing within Maryland, approval of this review will allow pharmacists, pharmacy personnel, and pharmacies to meet the demand for health care services and continue to be a gateway for patients to access quality care. Maryland pharmacists have been administering vaccines since October 2020, when the U.S. Department of Health and Human Services (HHS) issued guidance related to the HHS Declaration Under the Public Readiness and Emergency Preparedness (PREP) Act for Medical Countermeasures Against COVID-19. This federal guidance authorized qualified pharmacy technicians, acting under the supervision of a qualified pharmacist, to administer Food and Drug Administration (FDA)-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older and to administer FDA-authorized or FDA-licensed ACIP-recommended vaccines to persons ages three through 18 according to Advisory Committee on Immunization Practice's (ACIP's) standard immunization schedule.[1] In August 2021, this temporary federal authority was expanded to authorize qualified pharmacy technicians to administer seasonal influenza vaccines, under the supervision of a qualified pharmacist, to persons ages 19 and older consistent with ACIP recommendations.[2] As beneficial as this temporary federal authority has been in expanding access to care and relieving some of the burden on an overstressed

[1] Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing (October 20, 2020), https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf

[2] Eighth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID–19 (August 4, 2021), https://www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-16681.pdf

100 Daingerfield Road
Alexandria, VA 22314-2888
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healthcare system, it is set to expire in 2024. Approval of this bill will make this temporary federal authority permanent under state scope of practice, and it expands the authority to cover adult immunizations beyond influenza and COVID-19 as well.

Over 90% of Americans live within five miles of a community pharmacy,[3] and more than any other segment of the pharmacy industry, independent community pharmacies are often located in underserved rural and urban areas. These pharmacies are frequently the most accessible healthcare providers in many Maryland communities and are vital in the provision of immunizations, testing, and other services. This bill will not only allow pharmacies to expand their vaccination capacity but could also be an opportunity for patients without a medical home or primary care provider to be plugged in to the healthcare system and to access other services they might not otherwise receive.

NCPA strongly supports the Maryland Pharmacy Association in their advocacy to make the federal PREP ACT authorities permanent for Maryland pharmacists to independently order and administer vaccinations. We appreciate the bill's sponsor, Senator Augustine, for his attention to this important issue and we urge approval from this committee.

Sincerely,

Belawoe Akwakoku
State Government Affairs Manager
National Community Pharmacists Association

[3] NCPDP Pharmacy File, ArcGIS Census Tract File, NACDS Economics Department.

PowerPoint Explanation of PREP Act in Maryland_SPe

Uploaded by: cailey locklair

Position: FAV

Maintain Maryland's Access to Pharmacy Vaccines

Senator Malcolm Augustine and Delegate Lesley Lopez

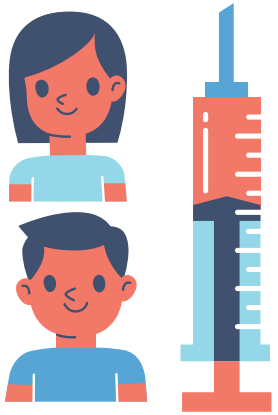
SB372/HB1234:

Health Occupations – Pharmacists – Administration of Vaccines

The Federal Public Health Emergency expires May 11.

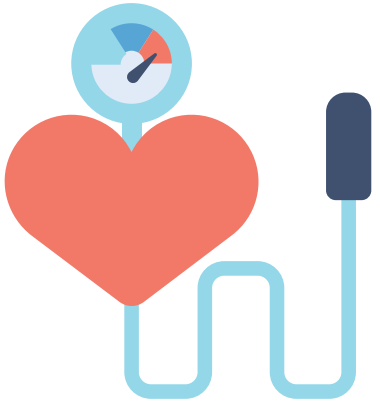
MARYLAND ASSOCIATION OF CHAIN DRUG STORES

When the US shut down in 2020,
pharmacies stayed open and provided Marylanders the critically needed healthcare services they now expect – **including 3.6 MILLION immunizations**

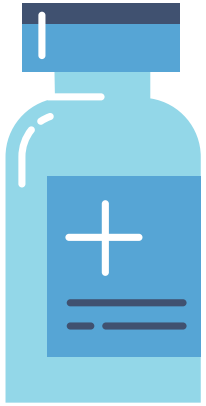


vaccine services

testing services



health screenings



needed medications

counseling on
important health issues

What is the PREP Act?

- The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the US Secretary of the Department of Health and Human Services to issue a PREP Act declaration to address a public health emergency.
- March 17, 2020, a PREP Act Declaration was issued to deal with COVID-19.
- April 20, 2020, pharmacists authorized to order and administer FDA-authorized COVID-19 tests.
- On August 20, 2020, the PREP Act was amended to allow pharmacists to provide a large number of health services including ACIP-recommended vaccinations to patients 3 years and older.
- On October 20, 2020, pharmacy technicians and pharmacy interns were authorized to administer childhood vaccines, COVID-19 vaccines, and COVID-19 testing; on August 4, 2021, they were further authorized to administer seasonal flu vaccines.
- The PREP Act preempts state law.
- In 2021, the Maryland legislature codified pharmacists' ability to immunize children down to the age of 3. The bill will sunset June 1 of this year.
- The separate Federal Public Health Emergency ends May 11, 2023.

National Proven Track Record of Safety and Patient Trust
"We built it and they came"

- >300 million COVID-19 vaccinations administered nationally to date in EVERY State – more than 3.6 million in Maryland alone
- >20,000 COVID-19 testing sites nationwide
- Thousands of locations nationwide providing access to COVID-19 antivirals
- Pharmacies provide more than 2 of every 3 COVID-19 vaccine doses
- >30% of children ages 5 to 11 who have received their COVID-19 vaccination have done so at a pharmacy
- 50% of pharmacy COVID-19 vaccination sites located in areas with high social vulnerability
- 70% of pharmacy testing sites in areas with moderate to severe social vulnerability
- >40% of those vaccinated at pharmacies were from racial and ethnic minority groups
- Medicare beneficiary claim data from Omnisys shows that pharmacies had a 31% greater impact on COVID-19 vaccines in rural areas where there is less access to care
- Located in nearly every community in MD, and open after work and school and on weekends without an appointment necessary

In Maryland and other states, these significant contributions were largely made possible by flexibilities granted during the Public Health Emergency under the Federal PREP Act declaration. Without action, these flexibilities will expire, rolling back essential and equitable access for the American people.

Marylanders now *expect* more healthcare services from their neighborhood pharmacy

- To provide the public with the level of services they have come to expect, Maryland lawmakers should permanently codify the PREP Act.
- On January 30th, President Biden announced that the Public Health Emergency will end on May 11, 2023, likely beginning a cascade of rollback on pandemic flexibilities.
- The public now expects point-of-care testing and a full portfolio of vaccine services at pharmacies, which requires the full use of the skills and expertise of the pharmacy team
- Current Maryland law does not match the allowances in the PREP Act and will leave critical gaps in care resulting in public confusion and frustration around access if it expires before these services are permanently allowed in our State.

Gaps in MD Law vs. PREP Act Authorities

	Authorized under PREP Act	Authorized under MD Law
Pharmacist order & administer vaccines	• COVID; 3 yrs and older • ACIP-recommended (including flu); 3-18 yrs	• Flu; 9 yrs and older (11+ with prescription) • Specific vaccinations under written protocol
Pharmacy intern administer vaccines	• COVID; 3 yrs and older • ACIP-recommended (including flu); 3-18 yrs	• Flu; 9 yrs+ under pharmacist supervision & written protocol
Pharmacy technicians administer vaccines	• COVID; 3 yrs and older • ACIP-recommended (including flu); 3-18 yrs • Flu to adults	• Not authorized
Pharmacist order & administer COVID-19 test	• Authorized	• Not Authorized
Pharmacy technician and pharmacy interns administer COVID-19 test	• Authorized	• Not Authorized
Pharmacists provide treatment per CLIA-Waived Test Results (i.e. Tamiflu for positive flu test)	• Yes	• Not Authorized

Safety and the Bill's Requirements

The PREP Act and this bill requires the following for immunizations administered by pharmacy personnel:

- A 20 hour training program, including injection technique, clinical evaluation of indications and contraindications of vaccines and the recognition and treatment of emergency treatment of reactions
- CPR certification
- Continuing education
- All healthcare providers MUST report into the State's Immunet system
- Record keeping and corresponding regulations adopted by The Board of Pharmacy
- Informs each patient and adult caregiver the importance of well-care child visits and refers them when appropriate

- **<u>STATE BY STATE PREP ACT POLLING RESULTS</u>**
- (survey commissioned by NACDS and conducted by Morning Consult December 7-12, 2022;)**Vaccine-Specific Questions:**
- ***Do you support or oppose pharmacists doing each of the following? Administering***
- ***COVID-19 vaccinations***
- % who support in:
- WV: 70%
- MN: 79%
- MD: 82%
- MI: 76%
- OH: 76%
- PA: 78%
- ***Do you support or oppose pharmacists doing each of the following? Administering***
- ***routine vaccinations (i.e., flu vaccinations, Tdap, tuberculosis)***
- % who support in:
- WV: 80%
- MN: 84%
- MD: 85%
- MI: 82%
- OH: 82%
- PA: 83%

APhA_Comments.SB372.FIN.pdf
Uploaded by: Michael Murphy
Position: FAV

APhA
American Pharmacists Association

February 27, 2023

[submitted electronically via: mgaleg.maryland.gov]

The Honorable Senator Melony Griffith
Chair, Finance Committee
Miller Senate Office Building, 3 East Wing
11 Bladen Street
Annapolis, MD 21401

RE: SB 372 (Augustine) – Pharmacists - Administration of Vaccines – SUPPORT

Dear Chair Griffith, Vice Chair Klausmeier, and members of the Finance Committee:

The American Pharmacists Association (APhA) appreciates the opportunity to submit proponent testimony on Senate Bill (SB) 372 (Senator Augustine). This bill will codify pharmacists' authority to order and administer vaccines to patients between three years old and 18 years old, if certain requirements are met. Pharmacists currently have this authority in Maryland during the federal public health emergency due to Declarations under the Public Readiness and Emergency Preparedness (PREP) Act. However, based on recent federal guidance, the federal authority under the PREP Act may be expiring in as early as 73 days, on May 11, 2023, which will interrupt patients' access to vaccines who have come to rely on pharmacists to order and administer vaccinations.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care and enhance public health. In Maryland, with 5,220 licensed pharmacists and 6,430 pharmacy technicians, APhA represents the pharmacists, student pharmacists, and pharmacy technicians that practice in numerous settings and provide care to many of your constituents. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-based, patient-centered care. APhA inspires, innovates, and creates opportunities for members and pharmacists worldwide to optimize medication use and health for all.

We also support the submitted testimony from the Maryland Pharmacists Association (MPhA).

Maryland pharmacists have been ordering and administering vaccines for patients between three years old and 18 years old since August 2020, when the U.S. Department of Health and Human Services (HHS) issued the third amendment to the HHS Declaration under the PREP Act for Medical Countermeasures Against COVID-19. This amendment authorized pharmacists to "order and administer any vaccine that the

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pharmacist.com

Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule (ACIP recommended vaccines)."[1] As beneficial as this temporary federal authority has been in expanding access to care and relieving some of the burden on an overstressed healthcare system, it is set to expire as early as May 11, 2023. SB 372 makes this temporary federal authority permanent under pharmacists' state scope of practice to minimize interruptions to patient access to preventive vaccines, lower health care costs and ensure Maryland can continue to meet its public health needs.

For these reasons, APhA supports SB 372 and respectfully request your "AYE" vote. If you have any questions or require additional information, please don't hesitate to contact E. Michael Murphy, PharmD, MBA, APhA Advisor for State Government Affairs by email at mmurphy@aphanet.org.

Sincerely,

E. Michael Murphy, PharmD, MBA
Advisor for State Government Affairs
American Pharmacists Association

cc: Senator Katherine Klausmeier, Vice Chair
Senator Pamela Beidle
Senator Arthur Ellis
Senator Dawn Gile
Senator Antonio Hayes
Senator Stephen S. Hershey, Jr.
Senator Benjamin F. Kramer
Senator Clarence K. Lam
Senator Johnny Mautz
Senator Justin Ready
Michael Baxter, APhA Acting Head of Government Affairs

[1] Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 (August 24, 2020), https://www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf.

4a - SB 372 - FIN - MDH - LOS .pdf
Uploaded by: State of Maryland (MD)
Position: FAV

Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 28, 2023

The Honorable Melony Griffith
Chair, Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401-1991

RE: SB 372 - Health Occupations – Pharmacists – Administration of Vaccines – Letter of Support

Dear Chair Griffith and Committee Members:

The Maryland Department of Health (MDH) submits this letter of support for Senate Bill (SB) 372 - Health Occupations – Pharmacists – Administration of Vaccines. SB 372 extends the current state and federal authority of pharmacists who meet certain training and other requirements to administer vaccinations to children ages three years old and older.

Vaccinations are one of the most important public health interventions. Pharmacists have demonstrated that they can safely administer vaccinations to children as young as three years old.[1] While coverage rates for routine childhood vaccines are relatively high in Maryland compared to other states, gaps still exist.[2] One method to address gaps is ensuring access to vaccinations at convenient times and locations.[3] Pharmacies are located throughout the state, including in areas with a lack of pediatricians or other health care providers. Pharmacies also often operate after the usual hours of some medical practices, making them convenient settings for vaccinations for working parents and adults.[4]

In other states, questions have been raised about communication between pharmacists providing vaccinations and physicians caring for patients. However, in Maryland, pharmacists administering vaccinations are required to report vaccinations to the state's immunization information system, ImmuNet, where providers and their patients can access immunization history. Based on data obtained from ImmuNet, 98% of vaccine doses reported by pharmacists are available within ImmuNet within seven days which suggest information is readily available to other health care care providers.

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[1] *The Prep Act and Covid-19, Part 2: The Prep Act Declaration ... - Congress*. https://crsreports.congress.gov/product/pdf/LSB/LSB10730.

[2] "ChildVaxView Interactive Child Vaccination Coverage." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 28 Sept. 2020, https://www.cdc.gov/vaccines/imz-managers/coverage/childvaxview/interactive-reports/index.html.

[3] Goad, Jeffery A., et al. "Vaccinations Administered during off-Clinic Hours at a National Community Pharmacy: Implications for IncreasingPatient Access and Convenience." *Annals of Family Medicine*, The Annals of Family Medicine, 1 Sept. 2013, https://www.annfammed.org/content/11/5/429.short.

[4] Kuehn, Michael, et al. "Assessing Barriers to Access and Equity for Covid-19 Vaccination in the US - BMC Public Health." *BioMed Central*, BioMed Central, 3 Dec. 2022, https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-022-14636-1.

MDH believes that pharmacists can safely expand access to a range of vaccines and are important in strengthening Maryland's immunization infrastructure by addressing vaccination gaps and inequities in our state.

If you would like to discuss this further, please contact Megan Peters, Acting Director of Governmental Affairs at megan.peters@maryland.gov or (410) 260-3190.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary

4b - SB 372 - FIN - PHARM - LOSWA.pdf
Uploaded by: Maryland State of
Position: FWA

Maryland
DEPARTMENT OF HEALTH
Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

MARYLAND BOARD OF PHARMACY
Jennifer L. Hardesty, PharmD, FASCP, Board President — Deena Speights-Napata, MA, Executive Director

February 28, 2023

The Honorable Melony Griffith
Chair, Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401-1991

RE: Senate Bill 372 – Health Occupations – Pharmacists – Administration of Vaccines

Dear Chairwoman Griffith and Committee Members:

The Maryland Board of Pharmacy (Board) respectfully submits this letter of support with amendments for Senate Bill (SB) 372 – Health Occupations – Pharmacists – Administration of Vaccines.

SB 372 would permit pharmacist administration of a vaccine listed on the Centers for Disease Control and Prevention's Recommended Immunization Schedule or approved by the Food and Drug Administration (FDA) to an individual who is at least three years old but under the age of eighteen. § 12-508(a)(1). SB 372 would require a pharmacist to complete a practical training program of at least twenty hours that is approved by the Accreditation Council for Pharmacy Education (ACIP), maintain a current certificate in basic cardiopulmonary resuscitation, and complete two hours of ACIP-approved continuing education credits related to immunizations during each license renewal period. § 12-508(a)(1). SB 372 would require a pharmacist to comply with record-keeping requirements and provide information regarding the importance of well-child visits with a pediatric primary care provider. § 12-508(a)(1).

SB 372 would extend pharmacist administration of adult vaccines to those approved by the FDA. § 12-508(a)(2). SB 372 would remove the requirement that a pharmacist develop a vaccine-specific written protocol prior to administering a vaccine. § 12-508(a)(2).

SB 372 would remove the requirement to report administration of an influenza vaccine to a patient's primary care provider. § 12-508(a)(3).

The Board supports administration of vaccines by appropriately trained licensed pharmacists.

Proposed language would require a pharmacist to obtain "a current certificate in basic cardiopulmonary resuscitation" prior to administering a vaccine to an individual who is at least three years old but under the age of eighteen, while current language requires the Board to adopt regulations that require a pharmacist to verify certification "in basic cardiopulmonary resuscitation through in-person classroom instruction" for children and adults. *Compare* § 12-508(a)(1)(iii) with § 12-508(b)(2)(ii). The Board submits that "in-person classroom instruction" is more appropriate and robust than "a current certificate in basic cardiopulmonary resuscitation."

Based on the above-mentioned item, the Board recommends the following amendment:

Amendment 1
On page 2, strike lines 15 – 16 beginning with "THE PHARMACIST HAS" and ending with "RESUSCITATION."

With the proposed amendment, the Board respectfully requests a favorable report on SB 372.

If you would like to discuss this further, please do not hesitate to contact Deena Speights-Napata, MA, Executive Director at deena.speights-napata@maryland.gov or (410) 764-4753.

Sincerely,

Deena Speights-Napata, MA
Executive Director

Pfizer-real-data-released.pdf
Uploaded by: Ayo Kimathi
Position: UNF

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

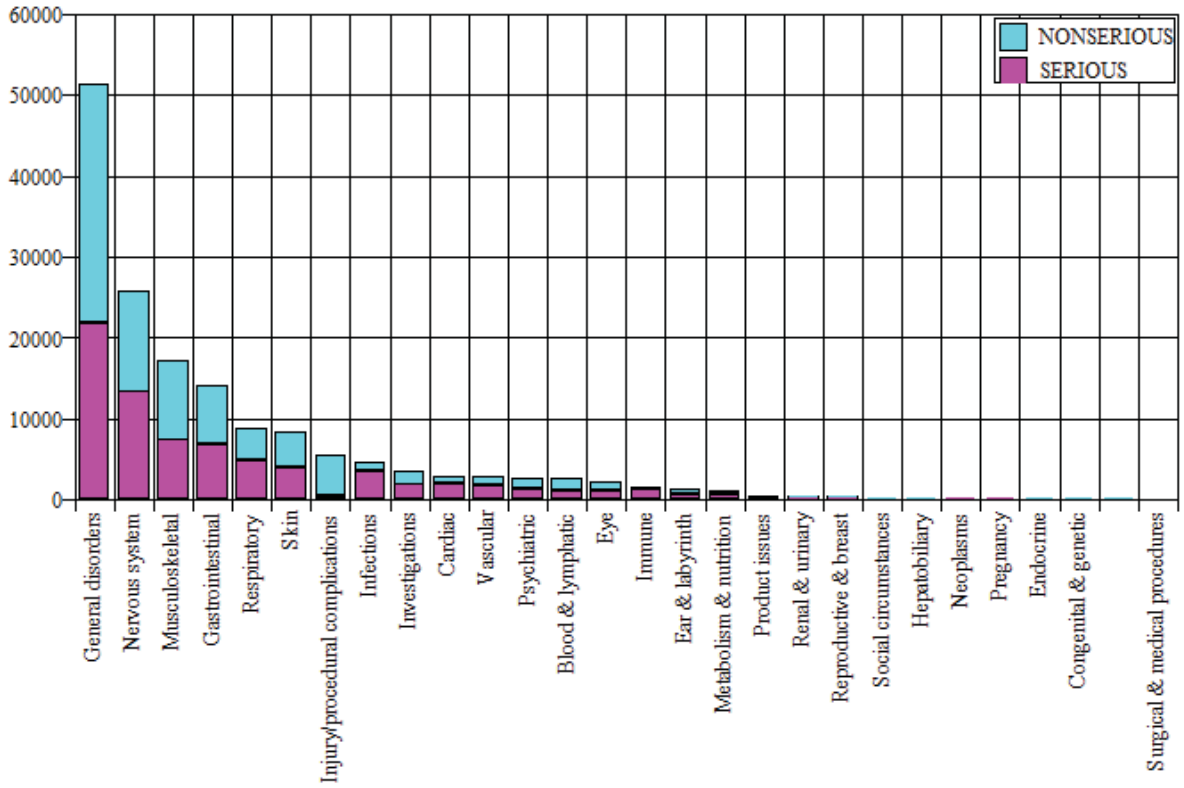

Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
Use in Paediatric Individuals <12 Years of Age	<u>Paediatric individuals <12 years of age</u> • Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; • Country of incidence: UK (29), US (3), Germany and Andorra (1 each); • Cases Seriousness: Serious (24), Non-Serious (10); • Gender: Females (25), Males (7), Unknown (2); • Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; • Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). • Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.
Vaccine Effectiveness	Company conventions for coding cases indicative of lack of efficacy: The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below: • PT "Vaccination failure" is coded when ALL of the following criteria are met: o The subject has received the series of two doses per the dosing regimen in local labeling. o At least 7 days have elapsed since the second dose of vaccine has been administered. o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). • PT "Drug ineffective" is coded when either of the following applies: o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19". o It is unknown: ▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling; ▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.); ▪ If 7 days have passed since the second dose; o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete. Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code "Drug ineffective"	Code "Vaccination failure"
Scenario Not considered LOE	Scenario considered LOE as "Drug ineffective"	Scenario considered LOE as "Vaccination failure"

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

Drug ineffective cases (1649)

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness. ***Vaccination failure cases (16)*** • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: o Within 7 and 13 days: 8 subjects; o Within 15 and 29 days: 6 subjects. COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases. Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
Anaphylactic Reactions *Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria*	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs *Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*	• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Dermatological AESIs *Search criteria: PT Chillblains; Erythema multiforme*	• Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Facial Paralysis *Search criteria: PTs Facial paralysis, Facial paresis*	• Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each); • Number of relevant events[k]: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Musculoskeletal AESIs *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis*	• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Other AESIs *Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient*	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*
Renal AESIs *Search criteria: PTs Acute kidney injury; Renal failure.*	• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Stroke *Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents*	• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

  Medication error case outcomes:

  - Fatal (7)[3],
  - Recovered/recovering (354, of which 4 are serious),
  - Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

February 27 testimory SB 0372.pdf
Uploaded by: Brian Finglass
Position: UNF

February 27, 2023

To the Honorable Committee members:

Re: My testimony regarding SB 0232

Dear Honorable Committee Members,

I am a 64 year old lifelong Maryland resident. I am opposed to this legislation for the following reasons.

- Decisions to vaccinate should remain between a citizen and a physician.
- There must be "informed consent"....meaning that the practitioner must be well versed in the current health and history of the patient.....and the patient must be of an age where they fully understand the ramifications of what the practitioner is saying. The practitioner must also present the pros and cons to the procedure and any alternative options.
- I do not see how a pharmacist would have the background information with regards to the patient in order to provide informed consent to the patient.
- I do not believe that a child under the age of 18 should be permitted to make medical decisions without the approval of their parent or legal guardian. This has been a historical practice by virtually all societies throughout history.

Please do not move forward with this legislation.

Respectfully submitted,

Brian Finglass

Testimony SB 372.pdf
Uploaded by: Brigitta MULLICAN
Position: UNF

Testimony from Brigitta Mullican Rockville, MD 20851 (LD-17)
February 27, 2023

Oppose SB 372, " Health Occupations - Pharmacists - Administration of Vaccines"

I agree with a pharmacist who wrote “pharmacists have already prostituted the profession by dispensing and administering the COVID "vaccine" without full informed consent.”

Here are additional reasons to oppose Bill 372.

1. Pharmacists are not trained or equipped to obtain an adequate medical history from each patient before administering vaccines to small children, particularly those aged 3-11. This bill would enable pharmacists to administer vaccines to small children without reviewing the child's medical chart, assessing contraindications, or evaluating the condition of the patient in the hours and days following the administration of the vaccine. Adverse reactions may be undetected and unreported to their primary care provider.

2. There is currently no state of emergency justifying the increased risk of expanding the scope of providers licensed to administer vaccines to children without assessing their full medical history and potential risk.

3. Although the CDC recently added Covid-19 vaccines to the recommended schedule for children, there is compelling evidence that Covid-19 vaccines confer more risk than benefit to patients aged 3-18. Pharmacists cannot accurately assess the risk versus benefit to pediatric patients they would be licensed to vaccinate with Covid-19 vaccines; nor would they have the means to monitor and assess possible adverse effects or evaluate previous medical history when potentially administering booster doses.

4. There is no evidence that expanding the scope of providers licensed to administer vaccines to small children improves health outcomes for those children, while conversely there is a demonstrable risk to children in doing so. There is no compelling reason to pass this bill when there is strong evidence that it will do harm.

Brigitta Mullican, coburgbrigitta@gmail.com

230227-SB372-pharm-vax-children.pdf
Uploaded by: Christine Hunt
Position: UNF

Christine Hunt and Jay Crouthers
1014 Dockser Drive
Crownsville, MD 21032

February 27, 2023

Maryland General Assembly
Members of the Finance Committee
Annapolis, MD

RE: SB 372-Health Occupations – Pharmacists – Administration of Vaccines

Dear Senators,

We oppose SB 372 and respectfully request that you vote against it.

Pharmacies are not doctor's offices and pharmacists are not doctors. They should not have the authority to **ORDER and vaccinate our children even more so without parental or guardian informed consent or knowledge.** The bill mentions nothing about the child having parental consent, only that the pharmacist will inform the child patient and adult caregiver accompanying the child to visit with a primary care provider.

Childhood vaccination rates in Maryland are among the highest in the nation between 90% and 98%. Doctors' offices are meeting any public need for childhood vaccination providers. There is no need for pharmacists to vaccinate.

This bill was originally part of an Emergency Use Authorization bill which was intended to expire by the end of 2022. It did not pass in 2022 and there is no need for a continued Emergency Use Authorization bill for a pandemic which has passed.

We strongly oppose this bill and ask that you vote against it.

Sincerely,

Christine Hunt and Jay Crouthers

2023 SB0372 - Kijesky-OPPOSED.pdf
Uploaded by: Crystal Kijesky
Position: UNF

Crystal Kijesky
11980 Provident Drive
LaPlata, MD 20646

SB0372 – OPPOSED

I am against proposed bill SB372 and ask that you give it an unfavorable report.

SB372 proposes to give vaccinations for minor children at a pharmacy.

I propose you go to a pharmacy and watch the timings and interactions between customer and pharmacy employees. In Charles County, we do not even have a 24 hour pharmacy any longer because there aren't enough pharmacists to work.

Many times, I have gone to fill my prescriptions after a sick or urgent care visit and the wait time is hours. Two-to – three hours for something simple and standard like amoxicillin.

Pharmacists are so very busy already, adding routine childhood vaccinations will be an even more risky business putting children at risk of vaccine mix- ups, vaccine injury to their arms. Children already are required, by law, to have certain vaccinations before they enter school. This should be done at a pediatrician's office where a thorough background and relationship is established because health care is more than vaccinations.

I belong to a Facebook group of parents whose children have multiple life-threatening allergies. MANY did not know their children had anaphylaxis to ingredients until AFTER certain vaccinations, requiring them to seek emergency care at a hospital. In our family, we carry epinephrine pens for medical emergencies.

I cannot imagine the possible injuries to children, up to death, because pharmacists do not have time to search background history on these children and the time to monitor children for 30 mins after their shots, which some are required to do in a pediatrician's office.

I urge you to please issue an unfavorable report on SB0372

Sincerely,
Crystal Kijesky
LaPlata, MD

Unfavorable SB 372.pdf
Uploaded by: Daniela D'Orazio
Position: UNF

Hello Senate Finance Committee,

I am here opposing SB372
There are several reasons why this bill should be opposed.
Retail pharmacists are overworked and already have the burden of excess work, long shifts, no breaks, and constant interruption. There is clearly a safety issue every time a pharmacist has to change focus from prescription checking to patient consultation, insurance claim support, staffing issues, health and beauty aid inquiries, and vaccination requests.
For example, providers were asked to monitor Covid-19 vaccine recipients for 15-30 minutes for signs of anaphylaxis. However, when my husband received the vaccine at Safeway, his interaction with the pharmacist lasted 30 seconds. The shot was administered, and she was off checking prescriptions, answering phones, and ringing up customers. Any anaphylaxis would have gone unnoticed as he was left alone, and went about shopping immediately after vaccination.
With children, immediate resuscitative care is crucial during anaphylaxis or other severe adverse reaction to medication. Pharmacists do not have the training or supplies to provide care during this situation.

As a parent, I am dismayed that the bill would allow a child to receive vaccination with a “caregiver” present and not a parent or legal guardian. The parent must manage the health and wellness of their child, and in no way should the state undermine that relationship. This bill is simply a back-door effort to allow childhood consent to vaccination as was allowed in SB378, to which I also am vehemently opposed (and ecstatic it was retracted).

In closing, please retract Senate Bill 372 immediately to promote parent’s rights and the safety of our patients receiving pharmaceutical care.

Sincerely,

Daniela D’Orazio

SB372.pdf
Uploaded by: Deborah Hopp
Position: UNF

My name is Deborah Hopp. I am a wife, mother, and grandmother. I am also a Baltimore City ESOL teacher. I oppose Senate Bill SB372.

This bill violates a parent's rights to make decisions on behalf of their children. Parents and guardians, solely, should be making the decisions concerning vaccinations for their children-NOT the pharmacist. This bill does not require informed parental consent. The bill was filed as an "Emergency Bill, but there is NO longer an EMERGENCY. Childhood vaccination rates in Maryland are among the highest in the nation. Furthermore, pharmacists are NOT doctors! They do not know the child's medical history and do not have a medical relationship with that child or the child's family. The pharmacists are not qualified to deal with a child who has a serious adverse reaction and has limited liability protection. In addition, it is NOT specified who is billed for such procedures. In closing, PARENTS are responsible for their child's health and well-being, not pharmacists. This bill MUST be withdrawn, and no further proceedings or amendments should be made concerning these emergency use vaccines in regards to a pharmacist having such authority.

UNFAV_SB372.pdf
Uploaded by: Denee Daly
Position: UNF

UNFAV SB372
Denee Daly
Street, MD

UNFAV SB372 / HB1232: Health Occupations- Pharmacists- Administration of Vaccines

I am writing to express my opposition to SB 372 / HB 1232 Health Occupations- Pharmacists- Administration of Vaccines that would allow pharmacists to vaccinate children age three and over without a doctor's prescription.

Children already have access to receive vaccines at doctor's offices, where an experienced, trained doctor can also assess the child's health. Pharmacists are not trained in that capacity.
Further, Pharmacies are crowded, chaotic and pharmacists are busy and focused on filling and managing prescriptions. Prescriptions should be the focus of pharmacists. When the ACIP (Advisory Committee on Immunization Practices) met in Sept 2022, pharmacists voiced concerns about administration of Covid bivalent boosters in pharmacies. Concerns included administration errors, the vaccination work being outside the normal pharmacy work flow. The ACIP meeting participants went further to say that the extra work was not conducive or practical in a busy pharmacy; this is why and how mistakes happen they said.
A reasonable conclusion is that even more mistakes will happen if pharmacists are burdened with giving pediatric vaccines, despite their best efforts.

Compounding the concern is that pharmacists are not pediatricians. They are not trained in the assessment of vaccine appropriateness and readiness. We must not allow children to be endangered that way.

Shoulder injuries need to also be considered. Shoulder injuries related to vaccine administration are on the rise with the advent of pharmacies giving immunizations. There is a growing number of compensations by the federal government with more people getting their immunization outside of the doctor's office.

In addition, managing and giving childhood vaccines scatters the focus of the pharmacist. It also hinders pharmacy customers from getting their pharmaceuticals if a pharmacist has to stop filling prescriptions every time a child walks up for a shot.

Pharmacists are not pediatricians and are not trained in the assessment of vaccine appropriateness and readiness. Pediatricians are specifically trained for this to reduce risk for serious harm or death. I think about the complicated schedule for childhood vaccines where they receive multiple shots at once and its not just the thought of a busy pharmacists without a pediatrician's training giving these shots, but also that the bill says the child can be vaccinated in the presence of a "caregiver". This should only by in the presence of a parent or legal guardian.

A child's best health outcomes happen when the parent and pediatrician work as a team, taking into consideration the health history, precautions, and any contraindications before making any medical decisions.

I respectfully request that you NOT pass **SB372** Health Occupations- Pharmacists- Administration of Vaccines forward to a vote.

Thank you,
Denee Daly
Street, Maryland resident

SB372.pdf
Uploaded by: Eleanor Jones
Position: UNF

Opposition to SB372 – Health Occupations – Pharmacists – Administration of Vaccines

I am writing in opposition to SB372 as children should have vaccinations approved first by their primary care physician under their parent's or guardian's presence. Pharmacists do not have readily available access to children's medical records, and because of this, they have no indication whether a child may suffer an adverse reaction to a vaccination that they administer to a child.

The state of emergency is over regarding Covid. There are no other health emergencies warranting that a pharmacist intervene in the administration of any vaccines that a child's primary care physician cannot do him/herself. If a child has no primary care physician assigned due to a variety of reasons including parent/guardian lack of insurance, free health clinics provide in house physicians to administer any necessary vaccines for children.

This bill is yet one more demonstration of the extreme overreach by state government to unnecessarily interfere into families' lives for the benefit of profits made by the pharmaceutical industries.

Eleanor Jones
Carroll County

Opposition Testimony on Md SB372.pdf
Uploaded by: Elizabeth Ohmen
Position: UNF

February 27, 2023

Dear Finance Committee:

I am writing to you today to strongly oppose SB 372.
I am a Maryland parent and voter and feel strongly that parental rights are being trampled on by this bill. Allowing children to get vaccinated without their parent present is subjugation of the public by the state. This would be a horrible precedent to set.

On top of this, there is very strong evidence emerging that the COVID-19 vaccines are dangerous beyond belief. This should be studied broadly and quickly!

Also, Pharmacists are already very busy professionals that should not be over burdened.

Thank you again for listening to us many citizens who Oppose Md SB 372.

Sincerely,
Elizabeth Ohmen, MD LD-15
Parent and Maryland Voter
Poolesville, MD

Opposition Testimony on Md SB372.pdf
Uploaded by: Elizabeth Ohmen
Position: UNF

February 27, 2023

Dear Finance Committee:

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I am a Maryland parent and voter and feel strongly that parental rights are being trampled on by this bill. Allowing children to get vaccinated without their parent present is subjugation of the public by the state. This would be a horrible precedent to set.

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Thank you again for listening to us many citizens who Oppose Md SB 372.

Sincerely,
Elizabeth Ohmen, MD LD-15
Parent and Maryland Voter
Poolesville, MD

testimony opposing SB372 pharmacists vax- 2023.pdf
Uploaded by: Emily Tarsel
Position: UNF

Emily Tarsell, LCPC

2314 Benson Mill Road
Sparks, Maryland 21152
February 28, 2023

Unfavorable SB372

Chairwoman Griffith, Vice Chair Klausmeier and Finance Committee Members,

I am Emily Tarsell, a mother, licensed therapist and founder of Health Choice Maryland, a large grassroots non-profit organization that advocates for health choice. We oppose **SB 372** which violates parental rights and the right to informed medical consent.

HB 372 seeks to extend emergency use authorizations for a pandemic that no longer exists. This bill did not pass last year and there is even less justification for it this year. Childhood vaccination rates in Maryland have been and continue to be among the highest in the nation at 93% [1] So doctors are meeting the need and we don't need pharmacists to call the shots.

Busy pharmacists will not know the child's health history and they don't have the time or training to treat children. But youth and adolescents are the real target of this bill because they might be in a pharmacy without parents and could be enticed by sugar coated ads, bribes or fear stroking into being vaccinated when they are not able to evaluate the risks.

For example, consumers are poorly informed and misled about the risk/benefit of the HPV vaccine, Gardasil. I know from personal experience. Twelve years ago my daughter Christina and I were told that Gardasil was "safe effective and would prevent cervical cancer". Chris got the shots and died 18 days after her last injection. We were not told about the risks. It took my experts and attorney 8 years to overcame denial by the CDC but finally the government conceded that she died from her Gardasil shots. And by law, Pharma, doctors and pharmacists cannot be sued or held accountable.

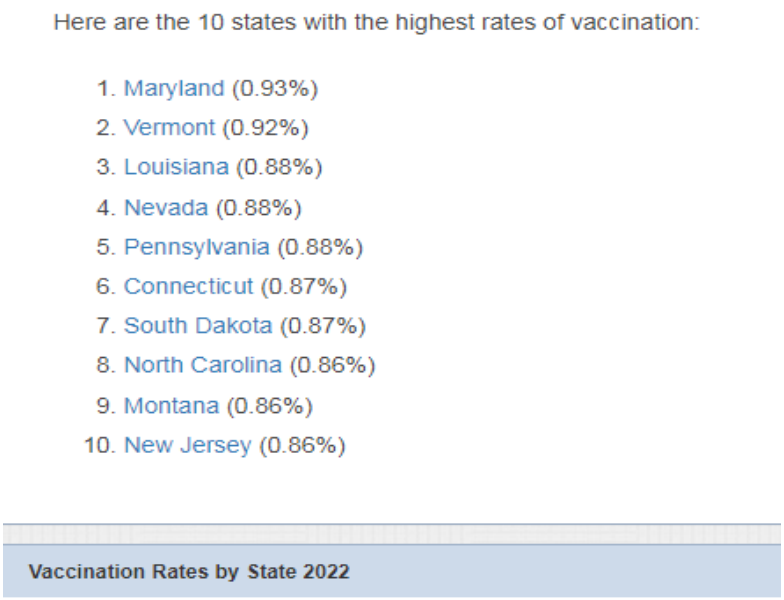
No child or teen can adequately evaluate the risk/benefit of vaccination. There were only 300 each of boys and girls 9-15 in the clinical trials for Gardasil. That is not comforting news. Young teens are more highly reactive to the neurotoxic aluminum in the vaccine which can induce autoimmune disorders. There are thousands of reports of serious adverse events including deaths following HPV vaccination. Weighing the risks and benefits should clearly be made on an individual basis with informed discussions between the parent/caretaker, child and the doctor.

Gardasil is a very expensive vaccine at $500 to $700 for the series, so pharmacists find it a lucrative market especially if the pesky need for informed parental consent is eliminated. While this might be great for provider **liability free profits**, it is bad for children's health.

Please vote **UNFAVORABLE for SB372.**

Thank you.
Emily Tarsell, LCPC

[1] https://worldpopulationreview.com/state-rankings/vaccination-rates-by-state



More documented information regarding the HPV vaccine, Gardasil, can be found here:

https://www.gardasilHPVtruths.com

Opposing SB372.pdf
Uploaded by: Eszter Szabo
Position: UNF

OPPOSE Senate Bill 372

Eszter Szabo
7608 Cayuga Avenue, Bethesda, MD 20817
February 27, 2023

This bill would open the door for pharmacists to administer influenza vaccine to children at least 9 years of age without parental consent and true informed consent. A 9-year-old has no capacity to decide if they need influenza vaccine. Most 9-year-olds have good immune system and don't need a influenza vaccine either. Parents and guardians should decide what vaccinations their children should receive. If a doctor prescribes a vaccine, and parents agree to that, the doctor should administer the vaccine.

The bill would allow pharmacists to order and inoculate children age 3 and over or age 11 and over certain authorized vaccines listed in the CDC and Prevention's Recommended Immunization Schedule or approved by the FDA including CV19 EUA vaccine without parental consent. This is dangerous and a serious breach of parental rights.

Pharmacists are not doctors or nurses. They are not the doctor of the children knowing their medical history. Pharmacists have a lot of responsibilities, adding this to their busy schedule is not a good idea. Recently I received a medication from my pharmacy which my doctor prescribed. At home when I wanted to take the medication, I noticed that the information didn't contain instruction on how many tablets to take per day. Since I couldn't reach the pharmacy nor my doctor, I needed to find the information myself on the internet. This was a simple case. What if a busy pharmacist is administering a vaccine to a 3-year-old? Any small mistake can cause serious harm for that child.

It was also filed as an "Emergency Bill" but there is no emergency. Covid is over.

Please vote against this bill which is trying to open the door of children being inoculated outside of doctor's offices and without parental consent.

Dear Senator Augustine and Finance Committee.pdf
Uploaded by: Frances Ichijo
Position: UNF

Dear Senator Augustine and Finance Committee,

As a Maryland Constituent, I am writing to you and other members of the Maryland Finance Committee to firmly OPPOSE Bill SB 372!

Pharmacies are not doctor's offices and pharmacists (and their assistants) are not doctors. They should not have the authority to ORDER and vaccinate our children even more so without parental or guardian informed consent.

I am opposed to expanding vaccination privileges for pharmacists to administer all vaccines to 3-year-olds and up. Pharmacists are already too busy to comply with mandatory counseling regulations, much less keep up with the constant interruption of vaccination. Interruption is a primary cause of dispensing errors. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6499714/. However, we all know retail chains will jump on this financial windfall and ask even more of their pharmacists and technicians, who are quitting now in record numbers. Please do not aggravate an already dangerous situation by adding this burden to our pharmacists.

Please oppose SB 372!

Thank you,

Fran Ichijo

Poolesville, MD

OPPOSE SB372.pdf
Uploaded by: Gala Meyerovich
Position: UNF

From: **Gala Meyerovich** gala_meyerovich@hotmail.com
Subject: OPPOSE SB372
Date: February 24, 2023 at 1:54 PM
To: malcolm.augustine@senate.state.md.us
Cc: melony.griffith@senate.state.md.us, katherine.klausemeier@senate.state.md.us, pamela.beidle@senate.state.md.us, arthur.ellis@senate.state.md.us, dawn.gile@senate.state.md.us, antonio.hayes@senate.state.md.us, steve.hershey@senate.state.md.us, ben.kramer@senate.state.md.us, clarence.lam@senate.state.md.us, johnny.mautz@senate.state.md.us, justin.ready justin.ready@senate.state.md.us

Dear Senator Augustine,

I strongly OPPOSE SB 372.

- Vaccination is a medical procedure that has do be done by doctors who have patients medical records and know their patients the best.
- Pharmacists are not doctors, they MUST NOT have authority to order vaccines for children.
- Pharmacies are busy chaotic places; chaos calls for unexpected mistakes as it has already happened many times!
- Childhood vaccination MUST BE done by pediatricians.
- If vaccination is done at a pharmacy, pediatricians may not have complete records of their patience that may lead to inaccurate treatments and misdiagnoses.'
- This bill promotes very low standards by requiring only 20 hours of practical training.

Please **withdraw** SB 372.

Thank you,
Gala Meyerovich
A resident of Montgomery County, MD
240-672-3274

hb1040-studybill.pdf
Uploaded by: Jenna Butler
Position: UNF

HOUSE BILL 1040

J2 ~~EMERGENCY BILL~~ 1lr0637
CF SB 736

By: **Delegate Kelly**
Introduced and read first time: February 5, 2021
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 7, 2021

CHAPTER _____

AN ACT concerning

Health Occupations – Pharmacists – Administration of ~~Vaccinations~~ Children's Vaccines – Study and Temporary Authority

FOR the purpose of authorizing, for a certain period of time, a pharmacist to administer certain vaccinations to an individual in a certain age group if certain requirements are met; ~~altering the age of an individual to whom a pharmacist may administer certain vaccinations; requiring a pharmacist to administer certain vaccinations under a written protocol; repealing the requirement that individuals in a certain age group have a certain prescription in order for a pharmacist to be allowed to administer a certain vaccination to the individual; authorizing a pharmacist to administer certain vaccinations to an adult; repealing the requirement that a certain written protocol be vaccine–specific; making this Act an emergency measure;~~ requiring the Prevention and Health Promotion Administration within the Maryland Department of Health, in consultation with the State Board of Pharmacy, to report to certain committees of the General Assembly on or before certain dates; establishing certain requirements for the reports; authorizing the Administration to use certain funding to contract with a certain institution to complete a certain report; requiring the Administration to consult certain stakeholders when completing a certain report; providing for the termination of a certain provision of this Act, subject to a certain contingency; making a conforming change; and generally relating to the administration of ~~vaccinations~~ children's vaccines by pharmacists.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–508

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Annotated Code of Maryland
(2014 Replacement Volume and 2020 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health Occupations

12–508.

(a) (1) **[**~~A~~ **SUBJECT TO SUBSECTION (C) OF THIS SECTION, A** pharmacist may administer an influenza vaccination to an individual who is at least 9 years old, in accordance with regulations adopted by the Board, in consultation with the Department.

(2)**]** ~~(I)~~ **[**A**]** **SUBJECT TO** ~~SUBPARAGRAPH (II) OF THIS PARAGRAPH~~ **SUBSECTION (C) OF THIS SECTION, A** pharmacist may administer a vaccination **[**that**]** ~~TO AN INDIVIDUAL WHO IS AT LEAST 3 YEARS OLD BUT UNDER THE AGE OF 18 YEARS IF THE VACCINE~~ is listed in the Centers for Disease Control and Prevention's Recommended Immunization Schedule **[**to an individual who:

(i) Is at least 11 years old but under the age of 18 years; and

(ii) Has a prescription from an authorized prescriber**]** ~~OR APPROVED OR AUTHORIZED BY THE U.S. FOOD AND DRUG ADMINISTRATION.~~

~~(II) A PHARMACIST SHALL:~~

~~1. ADMINISTER A VACCINATION UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH UNDER A WRITTEN PROTOCOL; AND~~

~~2. ADMINISTER AN INFLUENZA VACCINATION UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD, IN CONSULTATION WITH THE DEPARTMENT.~~

[(3)**]** ~~(2)~~ (i) Subject to subparagraph (ii) of this paragraph, a pharmacist may administer to an adult a vaccination that is:

1. Listed in the Centers for Disease Control and Prevention's Recommended Immunization Schedule; or

2. Recommended in the Centers for Disease Control and Prevention's Health Information for International Travel.

(ii) A pharmacist shall administer a vaccination under subparagraph (i) of this paragraph under a written protocol that**[**:

1. Is vaccine specific; and

2. Meets~~]~~ **MEETS** criteria established by the Department, in consultation with the Board, the Board of Physicians, and the Board of Nursing, in regulation.

~~[~~(4)~~]~~ ~~(3)~~ A pharmacist shall:

(i) Report all vaccinations administered by the pharmacist to the ImmuNet Program established under § 18–109 of the Health – General Article;

(ii) If the vaccination has been administered in accordance with a prescription, document at least one effort to inform the individual's authorized prescriber that the vaccination has been administered; and

(iii) ~~[~~For a vaccination administered under paragraph (2) or (3) of this subsection~~]~~ ~~EXCEPT FOR AN INFLUENZA VACCINATION ADMINISTERED UNDER PARAGRAPH (1)(I) OF THIS SUBSECTION~~, if the authorized prescriber is not the individual's primary care provider or if the vaccination has not been administered in accordance with a prescription, document at least one effort to inform the individual's primary care provider or other usual source of care that the vaccination has been administered.

(b) The Board shall:

(1) Set reasonable fees for the administration of vaccinations under this section; and

(2) Adopt regulations that require a pharmacist to submit a registration form to the Board that includes verification that the pharmacist:

(i) Has successfully completed a certification course approved by the Board that included instruction in the guidelines and recommendations of the Centers for Disease Control and Prevention regarding vaccinations; and

(ii) Is certified in basic cardiopulmonary resuscitation and obtained the certification through in–person classroom instruction.

(C) FROM JULY 1, 2021, TO JUNE 30, 2023, INCLUSIVE, A PHARMACIST MAY ADMINISTER A VACCINE TO AN INDIVIDUAL WHO IS AT LEAST 3 YEARS OLD BUT UNDER THE AGE OF 18 YEARS IF:

(1) THE VACCINE IS APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION;

(2) THE VACCINATION IS ORDERED AND ADMINISTERED IN ACCORDANCE WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES IMMUNIZATION SCHEDULES;

(3) THE PHARMACIST HAS COMPLETED A PRACTICAL TRAINING PROGRAM OF AT LEAST 20 HOURS THAT IS APPROVED BY THE ACCREDITATION COUNCIL FOR PHARMACY EDUCATION AND INCLUDES:

(I) HANDS–ON INJECTION TECHNIQUES;

(II) CLINICAL EVALUATION OF INDICATIONS AND CONTRAINDICATIONS OF VACCINES; AND

(III) THE RECOGNITION AND TREATMENT OF EMERGENCY REACTIONS TO VACCINES;

(4) THE PHARMACIST HAS A CURRENT CERTIFICATE IN BASIC CARDIOPULMONARY RESUSCITATION;

(5) THE PHARMACIST HAS COMPLETED A MINIMUM OF 2 HOURS OF CONTINUING PHARMACEUTICAL EDUCATION RELATED TO IMMUNIZATIONS THAT IS APPROVED BY THE ACCREDITATION COUNCIL FOR PHARMACY EDUCATION AS PART OF THE LICENSE RENEWAL REQUIREMENTS UNDER § 12–309 OF THIS TITLE;

(6) THE PHARMACIST COMPLIES WITH THE RECORD–KEEPING AND REPORTING REQUIREMENTS IN SUBSECTION (A)(4) OF THIS SECTION AND THE CORRESPONDING REGULATIONS; AND

(7) THE PHARMACIST INFORMS EACH CHILD VACCINATION PATIENT AND ADULT CAREGIVER WHO IS ACCOMPANYING THE CHILD OF THE IMPORTANCE OF WELL–CHILD VISITS WITH A PEDIATRIC PRIMARY CARE PROVIDER AND REFERS THE PATIENT TO A PEDIATRIC PRIMARY CARE PROVIDER WHEN APPROPRIATE.

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) On or before December 1, 2021, the Prevention and Health Promotion Administration within the Maryland Department of Health, in consultation with the State Board of Pharmacy, shall report to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, information the Administration determines is important for setting policies for authorizing pharmacists to administer vaccines to children, including:

(1) the number of vaccines administered to children by pharmacists in accordance with the requirements of Section 1 of this Act;

(2) the effectiveness and efficiency of ImmuNet; and

(3) whether the option for children to be administered vaccines by pharmacists has led to changes in well–child visits with pediatric primary care providers.

(b) (1) On or before December 1, 2022, the Prevention and Health Promotion Administration within the Maryland Department of Health, in consultation with the State Board of Pharmacy, shall report to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article:

(i) the capacity of the health care system to administer vaccines to children;

(ii) vaccination rates for children; and

(iii) community access to the administration of vaccines for children.

(2) In completing the report required under paragraph (1) of this subsection, the Administration shall:

(i) evaluate data from Maryland and other states that authorize pharmacists to administer vaccines to children on school–required vaccines and other vaccines administered to children; and

(ii) study the effectiveness and efficiency of ImmuNet, including by obtaining input from all health care providers that administer vaccines to children.

(3) In completing the report required under paragraph (1) of this subsection, the Administration shall consider public health models in which pharmacists, in both chain and independent pharmacies, can support and facilitate families in obtaining well–child visits from pediatric primary care providers, including partnerships with:

(i) local health departments;

(ii) pediatric primary care providers, including private practices and community health centers; and

(iii) school systems, including school–based health centers.

(4) The report shall address implementation recommendations, including:

(i) tracking multidose vaccines;

(ii) optimal physical space configurations to protect the privacy and safety of patients;

(iii) staffing requirements; and

(iv) processes for responding to adverse reactions.

(5) The Administration shall make recommendations regarding:

(i) whether the temporary authority established under Section 1 of this Act should be made permanent; and

(ii) ways to further integrate the use of ImmuNet in electronic health records to facilitate communication between pharmacists and pediatric primary care providers.

(c) In completing the report required under subsection (b) of this section, the Administration:

(1) may use available funding to contract with a public health research institution to complete the report; and

(2) shall consult with interested stakeholders, including:

(i) pediatric primary care providers;

(ii) pharmacists;

(iii) managed care organizations;

(iv) local health departments; and

(v) consumers.

SECTION 3. AND BE IT FURTHER ENACTED, That:

(a) If the Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 issued by the Office of the Secretary of the Department of Health and Human Services is repealed or otherwise expires before January 1, 2022, on April 30, 2022, with no further action required by the General Assembly, Section 1 of this Act shall be abrogated and of no further force and effect.

(b) The Prevention and Health Promotion Administration within the Maryland Department of Health shall notify the Department of Legislative Services within 5 days after receiving notice of the repeal or expiration of the amendment described in subsection (a) of this section.

~~SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has been passed by a yea and nay vote supported by three–fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is enacted.~~

SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2021.

Approved:

_____

Governor.

_____

Speaker of the House of Delegates.

_____

President of the Senate.

MDHreport1-studyperiod.pdf
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Position: UNF

Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

March 16, 2022

The Honorable Paul G. Pinsky, Chair
Education, Health and Environmental Affairs Committee
Miller Senate Office Building, 2 West
Annapolis, MD 21401

The Honorable Shane E. Pendergrass, Chair, Health and Government Operations Committee
House Office Building, Room 241
Annapolis, MD 21401

Re: SB 736/HB 1040 (Chapters 792 and 793 of the Acts of 2021) - Health Occupations - Pharmacists - Administration of Children's Vaccines - Study and Temporary Authority

Dear Chairs Pinsky and Pendergrass:

Pursuant to Health Occupations - Pharmacists - Administration of Children's Vaccines - Study and Temporary Authority (HB 1040/SB 736) (2021), the Maryland Department of Health (MDH) is directed to produce a report, in consultation with the State Board of Pharmacy, to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee. In accordance with § 2–1257 of the State Government Article, MDH must include information it determines is important for setting policies for authorizing pharmacists to administer vaccinations to children, including: (1) the number of vaccines administered to children by pharmacists in accordance with the requirements of Section 1 of this Act; (2) the effectiveness and efficiency of ImmuNet; and (3) whether the option for children to be administered vaccines by pharmacists has led to changes in well-child visits with pediatric primary care providers.

Md. Ann. Code Health-General Article §18–109 requires an ImmuNet program. The current ImmuNet platform was implemented in 2010 as a database to capture and record an individual's vaccination records and provide a web-based tool for healthcare providers and schools to keep their patient and/or student vaccinations up-to-date. Health-General Article §§12-508 and 18–109, respectively, require pharmacists and local health departments to report all vaccinations to ImmuNet. In October 2019, HB 316 (2019) amended the law to require vaccinations administered by all providers in Maryland be reported to ImmuNet with the exception of those administered in nursing facilities, assisted living programs, continuing care retirement communities, or medical day care programs. Since its inception, ImmuNet has captured over 74 million vaccinations and has nearly 8,000 registered organizations throughout the state. Additionally, providers in the federal Vaccines for Children (VFC) program are required to order vaccinations for their VFC eligible population in ImmuNet. Since the capability to support this was developed, VFC providers have ordered over 16 million vaccinations. ImmuNet serves

as the primary source for COVID-19 vaccination data, and all doses of COVID-19 vaccinations are ordered through ImmuNet.

Table 1 provides the following data from all time as measurements of ImmuNet's overall efficiency and effectiveness in surveilling vaccinations in the state: the total number of vaccinations administered by pharmacists to children, vaccinations recorded in ImmuNet, organizations registered with ImmuNet, vaccinations ordered in ImmuNet, and the percentage of providers reporting to ImmuNet. In accordance with Health-General Article §12–508, pharmacists are required to report all vaccinations administered to ImmuNet.

Table 1: Total Vaccinations, Providers, and Organizations Reported to ImmuNet, Maryland, 2018-2020

Indicator	CY 18	CY 19	CY 20
Vaccinations administered to children by pharmacists (<18 years of age)	33,519	33,507	70,016
Vaccinations recorded in ImmuNet	4,667,683	4,885,797	4,733,823
Organizations in ImmuNet	3,924	4,154	6,138
Vaccinations ordered in ImmuNet	1,072,708	1,168,669	1,172,299
Percent of providers reporting to ImmuNet	66%	69%	47%

MDH's Prevention and Health Promotion Administration and Maryland Medicaid worked together to provide data on well-child visits with pediatric primary care providers prior to and after the enactment of this legislation. This data is presented in Table 2.

Table 2: Medicaid Enrollees Well-Care Visits and Vaccinations, Maryland, 2018-2020

Indicator	CY 18	CY 19	CY 20*
Total Enrollees	564,000	565,922	564,057
Enrollees with a Well-Care Visit	338,510	345,143	295,786
Enrollees with a Vaccination from a Non-Pharmacy Provider	231,551	230,044	206,086
Enrollees with a Well-Care Visit and a Vaccination from a Non-Pharmacy Provider	208,685	208,894	185,732
Enrollees with a Vaccination from a Pharmacy	5,701	5,108	10,913
Enrollees with a Well-Care Visit and a Vaccination from a Pharmacy	3,739	3,398	6,138
Enrollees with Any Vaccination	234,938	233,343	213,800
Enrollees with a Well-Care Visit and Any Vaccination	210,364	210,633	188,981

**Service utilization in CY20 may be impacted by the COVID-19 pandemic*

The results of an analysis of Medicaid data conducted by The Hilltop Institute show that enrollees receiving vaccinations from a pharmacy increased in number while those receiving vaccinations in other settings declined during the study period. However, it is important to note that providers may submit fee-for-service (FFS) claims for up to 12 months after the date of service. Therefore, an insufficient period has passed to gather all claims and encounters rendered

for the entire measurement period. Data for this period are considered preliminary at this time. Additionally, service utilization in calendar year 2020 may be impacted by the COVID-19 pandemic.

If you have questions about this report, please contact Heather Shek, Director, Office of Governmental Affairs, at 410-767-5282 or heather.shek@maryland.gov.

Sincerely,

Dennis R. Schrader
Secretary

cc: Jinlene Chan, MD, MPH, FAAP, Deputy Secretary, Public Health Services
Steven R. Schuh, MA, Deputy Director for Health Care Financing Administration and Medicaid Director
Heather Shek, JD, MS, Director, Office of Governmental Affairs
Donna Gugel, MHS, Director, Prevention and Health Promotion Administration
Deena Speights-Napata, MA, Executive Director, Maryland Board of Pharmacy
David Blythe, MD, MPH, Director, Infectious Disease Epidemiology and Outbreak Response Bureau
Sarah Albert, Department of Legislative Services, 5 copies (MSAR # 13347)

SB 372-Butler-Unfavorable.pdf
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Position: UNF

SB 372 / UNFAVORABLE

Chair Griffith, Vice Chair Klausmeier, and Members of the Finance Committee-

Thank you for your time. I'm a Maryland parent and small business owner submitting this testimony to urge you to give SB 372 an unfavorable report. While there are many other issues with this legislation that I won't go into here, I would like to walk through the history of this legislation in the MD General Assembly as I think it is extremely relevant to your decision on whether or not it should move forward.

A version of this bill has come up for years. During the 2020 session, the proposed age was 9+ without a prescription and even then it did not have the support to pass. It was obvious from the supporting testimony that it was the potential financial gain, not the benefits for children's health, that was most attractive to pharmacies. During the hearing, Senator Augustine frankly stated that supporting pharmacies was part of the purpose of the bill. **It did not move forward.**

In August 2020, as part of the response to Covid-19, the federal PREP Act was amended by the Trump Administration to allow pharmacists to vaccinate children ages 3 and up. As with all emergency measures, it was intended for only a limited time. During the 2021 legislative session, legislation modeled after the PREP Act was submitted here as HB 1040/SB 736, intending to make pharmacists vaccinating children ages 3+ permanent in Maryland. Again the support for it was not there, and instead of passing outright, it was turned into a study so that the state could collect data while the federal emergency was allowing it anyway, and see if this was working or not working.

The 2021 study legislation *[please see attached highlighted copy]* **required that TWO reports** be completed by MDH and be submitted to the appropriate legislative committees.

The first report, due by December 1, 2021, was to include the following information:

- The number of vaccines administered to children by pharmacists;
- the effectiveness and efficiency of ImmuNet; and

- Whether the option for children to be administered vaccines by pharmacists has led to changes in well-child visits with pediatric primary care providers.

That report was submitted and is dated March 2022 *[please see attached highlighted copy of the one submitted report]*. While it is not as detailed as it should be, and ironically does not include any data from 2021 at all, there are few clearly concerning figures here- the number of vaccines received by Medicaid enrolled minors at a pharmacy doubled from 2019 to 2020, while the number of well-child visits for the same group dropped by almost 50,000 in that time period. Of course this may be impacted by Covid closures or missing data, but it definitely tells us that we NEED more information. This report also revealed that since 2018, the % of providers that report to ImmuNet has declined from almost 70% to less than half. This is an extremely dangerous and inefficient percentage. Timely and correct reporting to ImmuNet is essential for immunization safety and accuracy. The whole intent of that system is to avoid under- AND over- vaccination. It is Maryland law that all vaccines administered be reported to ImmuNet. It is extremely unwise to be expanding the network of immunizers for children, while leaving gaps in ImmuNet unknown or unaddressed at the same time.

There was also a second report that was due by December 1, 2022.

This more expansive report was to include, among other information: the capacity of the health care system to administer vaccines to children; community access to the administration of vaccines for children; evaluate data from Maryland and other states that authorize pharmacists to administer vaccines to children; AND study the effectiveness and efficiency of ImmuNet. MDH was instructed to consult with interested stakeholders, including consumers, in order to complete this report.

THIS REPORT HAS NOT, to date, been submitted by MDH as it was required to do.
If we haven't evaluated that information yet, and in fact DO NOT EVEN HAVE THAT INFORMATION yet, how can the legislature move forward with this bill? The study report we do have is extremely concerning and does not at all support moving SB 372 forward to permanent policy. **In 2021, this body decided that this concept needed to be studied, not**

passed. We still do not have the results of the study. The Maryland state of emergency has ended, the federal emergency is ending. What is the need for this?

I know that all of you take your commitment and responsibility as Senators very seriously. **There is an opportunity here for you, as the committee hearing this bill, to help ensure that Maryland's children are getting the thoughtful, beneficial legislation that they deserve from their state. Allowing an emergency measure- with so many clear issues- to become permanent Maryland law does not align with that goal. Please do not let SB 372 move forward.** Thank you.

- Jenna DeCesaris Butler
Anne Arundel County, Maryland

UNFAV_SB372.pdf
Uploaded by: Jennifer Morrison
Position: UNF

SB372
Jennifer Morrison
Havre de Grace, MD
Position: Oppose

I am a Maryland resident from Harford county and I strongly oppose this bill.

The CDC has posted a notice which describes:
“Who Should NOT Get Vaccinated with these Vaccines?
Because of age, health conditions, or other factors, some people should not get certain vaccines or should wait before getting them. Read the guidelines below for each vaccine.”
https://www.cdc.gov/vaccines/vpd/should-not-vacc.html

Many of the vaccines on the childhood vaccine schedule include contraindications, as described in the above mentioned notice, such as (although not limited to):
● severe, life-threatening allergies.
● is a child or adolescent 2 through 17 years of age who is receiving aspirin or aspirin containing products.
● Has a weakened immune system, or has a parent, brother, or sister with a history of hereditary or congenital immune system problems.
● Has gotten any other vaccines in the past 4 weeks.

Clearly, only the child’s doctor and child’s parent/s would be the only parties, together, who are able to determine the appropriateness of administering a pharmaceutical product, considering health history and contraindications.
A pharmacist has neither the education nor the qualifications to assess the child’s risk for health or death, and no amount of training could qualify him or her to determine this. The 20 hours of training detailed in this bill is simply preposterous!

UNFAVORABLE_SB0372_Helms_Jessica.pdf
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Position: UNF

UNFAVORABLE

SB0372 Health Occupations - Pharmacists - Administration of Vaccines

Jessica Helms

Capitol Heights, MD

I am writing to urge an unfavorable report on SB0372. This bill removes all safe guards for the children it would affect.

First, it removes the need for a prescription. Without one, parents would be able to skip well visits to get whatever shots the kids needed for school or sports. While this sounds like a good thing it, it isn't. Pediatricians are trained to see things in children that a hurried pharmacist might miss. A pharmacist won't be checking to see if the child already has a fever and recommend delaying a vaccine until the child is healthy as a pediatrician would. Giving a vaccine in a pediatricians office also means that nurses who are used to working with children and given 100s of shots a day can make the experience as stress free for the child as possible. Imagine how much more horrifying it would be for a child to be given a vaccine in Walmart in front of a line of strangers who, quite frankly, aren't going to want to hear their screaming or know what to do with the awkwardness of the situation.

Second, the bill allows for literally *anyone* accompanying the child to get the child vaccinated for *anything* the person with the child decides they need. This allows even a babysitter to take the kids she's watching to the CVS on the corner and get them flu shots during the $20 gift card incentives we see each year and walking away with one for each child in her care without ever even needing to consult the parent or legal guardian of the child. For people who have to rely on babysitting sites like care.com, this is a terrifying thing to have to add to that list of worries moms already have when leaving their child with someone new. No one other than the parent or legal guardian of a child should be able to make a medical decision for that child.

When I called Senator Augustine's office I was told the point of the bill was to make it easier for parents to get their kids vaccinated even if it meant sending a babysitter with the child to the pharmacy. What the bill fails to do is protect those same kids from people who would prey on them for extra cash in their pocket, from a parent with limited visitation who doesn't actually know what vaccines the child has received taking them down to get them vaccinated a second time "just in case" (notice that the flu shot doesn't need to be reported to their primary care doctor), or from a parent who doesn't want to bother with a well visit. Children need to see a doctor BEFORE a vaccine is administered to ensure they are healthy enough to receive it, not after.

Add to this the number of injuries currently on the rise due to pharmacists incorrectly giving a vaccine and we are going to see children with shoulder injuries that last a life time like we do with some adults, my grandmother included. She has vowed to never again get a vaccine in a

pharmacy after a pharmacist injured her with a flu shot. It's been eight years now and she still does not have full use of her arm. She gets them with her doctor and no one else.

https://www.pharmacytimes.com/view/compensation-growing-for-botched-vaccine-administration states, "Dr, Bodor noted that patients who receive vaccines at a pharmacy may be pulling their shirt down just a little, which could lead the pharmacist to administer the vaccine higher up on the shoulder. In contrast, patients receiving vaccinations in a physician's office may be dressed in a gown, which would allow for more space to administer the vaccine." With pharmacists already overworked, having them rush to give a four-year-old five shots at once while others are waiting in line is going to cause more injuries and more trauma for the child. I don't want MY child fearing going to Walmart or Target with me because she's afraid she'll get a shot there the first time she sees another child getting one.

Please return an UNFAVORABLE report on SB0372.

Jessica Helms

Capitol Heights, MD

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Position: UNF

Parents say Walgreens mistakenly injected them and their two kids with the Covid-19 vaccine instead of flu shot

By Amy Simonson and Madeline Holcombe, CNN

Updated 8:18 AM EDT, Thu October 14, 2021

NIH director makes plea to evangelical Christians

01:59 - Source: CNN

(CNN) — Joshua and Alexandra Price say they and their two children were mistakenly given the Covid-19 vaccine instead of a flu shot a week ago at their local pharmacy – and they are now dealing with some adverse symptoms.

The Prices took their 4- and 5-year-olds to the Walgreens in Evansville, Indiana, on October 4 for their yearly shots. About 90 minutes later the pharmacist called saying they had made a mistake. The entire family had been injected with adult doses of the Covid-19 vaccine.

“When they called us and told us that they had made a mistake and had given us the wrong shot, I was just in shock,” Alexandra Price said. “All I could say to them was, ‘What does this mean for my kids?’”

RELATED ARTICLE
Schools are new battleground in war of disinformation over Covid-19 vaccines

Although Alexandra and Joshua, already fully vaccinated since last April, were concerned for themselves, they were more worried about Sophia, 5 and Lukas, 4.

“Lukas started feeling sick before we even got home from Walgreens,” Alexandra said.

“He was feeling yucky, lethargic, and already had begun a fever,” Joshua added.

Joshua, Alexandra, Sophia and Lukas Price

The Pfizer/BioNTech vaccine is approved for people age 16 and older and has an emergency use authorization for people ages 12 to 15. Pfizer said in a tweet on October 7 that it had submitted a formal request for emergency use authorization for a smaller dosage of vaccine for children ages 5 to 11 to the Food and Drug Administration.

“They will probably do OK,” said Dr. Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine. “The difference is they got a three times higher dose of a vaccine than is being tested in clinical trials.”

“It is concerning they got a higher dose, and they have to be monitored, but they should do really well,” Hotez said. “There is a lot of data out there now in 5-year-olds and older.”

He added that Alexandra and Joshua’s extra dose of the vaccine is similar to receiving a booster shot.

After requesting that Walgreens give them proof of vaccination so that the family could show medical professionals what they were given in the case of an emergency, the Prices say Walgreens hesitated. “They wanted to get their legal department involved and did not want to give us those cards, so we got our own attorney,” Alexandra said.

Joshua explained that the cards were important proof for the doctors if the children continued to get sick. He said Walgreens gave them their cards the next day.

RELATED ARTICLE
FDA to take up Moderna, J&J Covid-19 booster questions, including mix-and-match shots

Walgreens’ spokesperson Kris Lathan released a statement to CNN saying that due to privacy laws, it could not comment on a specific event.

“Generally speaking, know that such instances are rare and Walgreens takes these matters very seriously,” the statement said. “In the event of any error, our first concern is always our patients’ well-being. Our multi-step vaccination procedure includes several safety checks to minimize the chance of human error and we have reviewed this process with our pharmacy staff in order to prevent such occurrences.”

Walgreens did not comment on how a vaccine mix-up could have occurred.

Symptoms did worsen for Sophia and Lukas, and the Prices took their children to see a

cardiologist.

“The children have experienced a number of adverse effects since receiving the Pfizer COVID-19 vaccine. Fever, body aches, cough, headaches, and nausea are among the symptoms the children are experiencing,” according to a statement released by the Prices’ attorney, Dan Tuley. “The 4- and 5-year-old are also under treatment of a pediatric cardiologist for tachycardia and elevated blood pressure, respectively.”

After a follow-up appointment Tuesday, Alexandra said that Lucas has improved but Sophia has worsened. “Her blood pressure is in the 98th percentile and she continues to have no energy.”

Alexandra and Joshua themselves continue to slowly recover from symptoms that set in shortly after the vaccination. Those symptoms include high blood pressure, fevers, chest pain, and headaches.

“It’s been well over a week and I still have high blood pressure and chest pain,” Joshua said. He said that he is being monitored by his doctor for the blood pressure and chest pains.

CNN tried contacting Pfizer for comment but did not hear back.

US

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01:59 - Source: CNN

(CNN) — Joshua and Alexandra Price say they and their two children were mistakenly given the Covid-19 vaccine instead of a flu shot a week ago at their local pharmacy – and they are now dealing with some adverse symptoms.

The Prices took their 4- and 5-year-olds to the Walgreens in Evansville, Indiana, on October 4 for their yearly shots. About 90 minutes later the pharmacist called saying they had made a mistake. The entire family had been injected with adult doses of the Covid-19 vaccine.

“When they called us and told us that they had made a mistake and had given us the wrong shot, I was just in shock,” Alexandra Price said. “All I could say to them was, ‘What does this mean for my kids?’”

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Although Alexandra and Joshua, already fully vaccinated since last April, were concerned for themselves, they were more worried about Sophia, 5 and Lukas, 4.

“Lukas started feeling sick before we even got home from Walgreens,” Alexandra said.

“He was feeling yucky, lethargic, and already had begun a fever,” Joshua added.

Joshua, Alexandra, Sophia and Lukas Price

The Pfizer/BioNTech vaccine is approved for people age 16 and older and has an emergency use authorization for people ages 12 to 15. Pfizer said in a tweet on October 7 that it had submitted a formal request for emergency use authorization for a smaller dosage of vaccine for children ages 5 to 11 to the Food and Drug Administration.

“They will probably do OK,” said Dr. Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine. “The difference is they got a three times higher dose of a vaccine than is being tested in clinical trials.”

“It is concerning they got a higher dose, and they have to be monitored, but they should do really well,” Hotez said. “There is a lot of data out there now in 5-year-olds and older.”

He added that Alexandra and Joshua’s extra dose of the vaccine is similar to receiving a booster shot.

After requesting that Walgreens give them proof of vaccination so that the family could show medical professionals what they were given in the case of an emergency, the Prices say Walgreens hesitated. “They wanted to get their legal department involved and did not want to give us those cards, so we got our own attorney,” Alexandra said.

Joshua explained that the cards were important proof for the doctors if the children continued to get sick. He said Walgreens gave them their cards the next day.

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Walgreens’ spokesperson Kris Lathan released a statement to CNN saying that due to privacy laws, it could not comment on a specific event.

“Generally speaking, know that such instances are rare and Walgreens takes these matters very seriously,” the statement said. “In the event of any error, our first concern is always our patients’ well-being. Our multi-step vaccination procedure includes several safety checks to minimize the chance of human error and we have reviewed this process with our pharmacy staff in order to prevent such occurrences.”

Walgreens did not comment on how a vaccine mix-up could have occurred.

Symptoms did worsen for Sophia and Lukas, and the Prices took their children to see a

cardiologist.

“The children have experienced a number of adverse effects since receiving the Pfizer COVID-19 vaccine. Fever, body aches, cough, headaches, and nausea are among the symptoms the children are experiencing,” according to a statement released by the Prices’ attorney, Dan Tuley. “The 4- and 5-year-old are also under treatment of a pediatric cardiologist for tachycardia and elevated blood pressure, respectively.”

After a follow-up appointment Tuesday, Alexandra said that Lucas has improved but Sophia has worsened. “Her blood pressure is in the 98th percentile and she continues to have no energy.”

Alexandra and Joshua themselves continue to slowly recover from symptoms that set in shortly after the vaccination. Those symptoms include high blood pressure, fevers, chest pain, and headaches.

“It’s been well over a week and I still have high blood pressure and chest pain,” Joshua said. He said that he is being monitored by his doctor for the blood pressure and chest pains.

CNN tried contacting Pfizer for comment but did not hear back.

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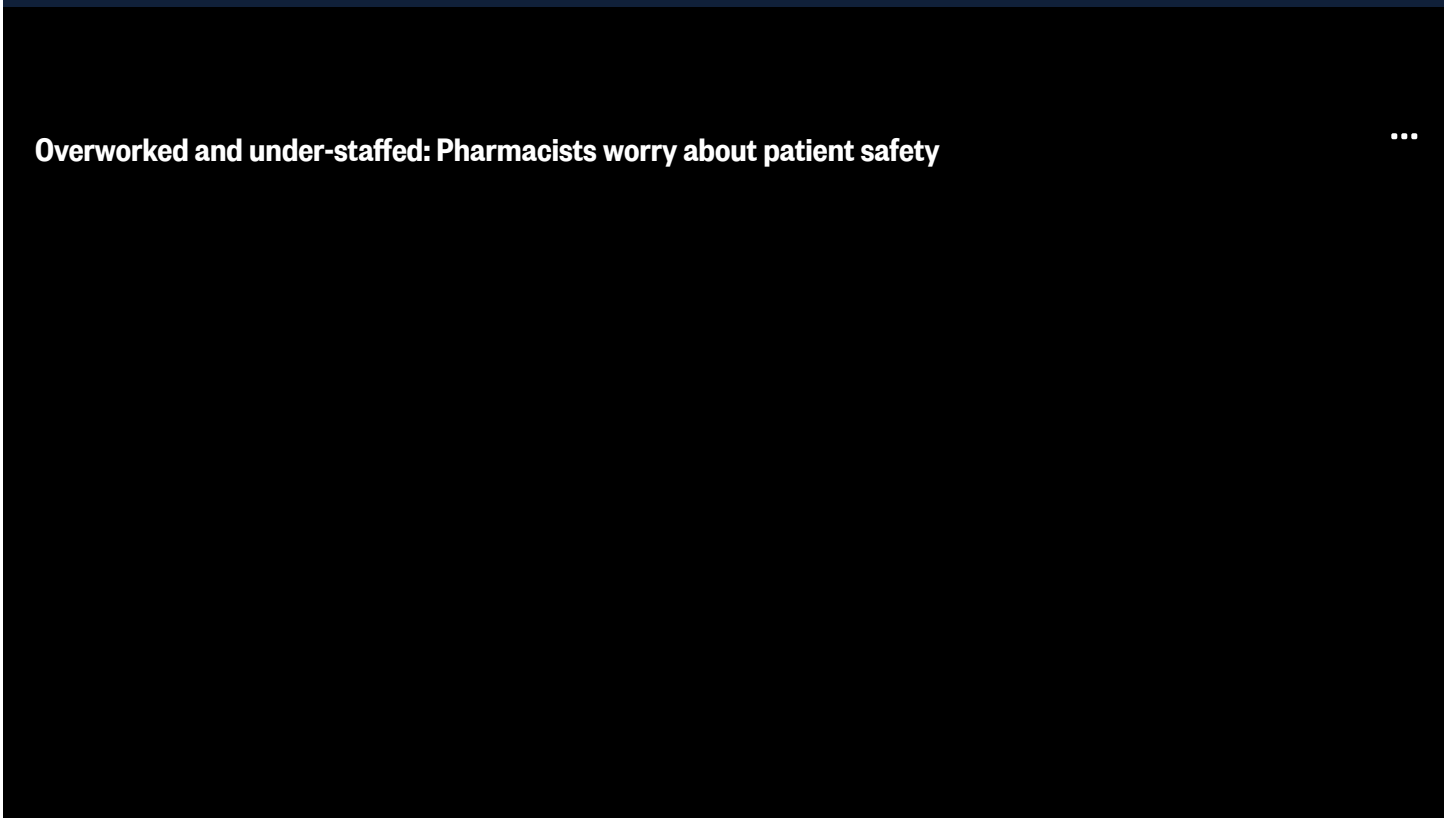
HEALTH CARE

Overworked, understaffed: Pharmacists say industry in crisis puts patient safety at risk

"We're going to have a fatal error somewhere," said a pharmacy technician in New York, "because we're doing too many things at once."



March 17, 2021, 4:31 AM KST

By Adiel Kaplan, Vicky Nguyen and Mary Godie

From the moment Marilyn Jerominski walks into her pharmacy every morning, her time is in demand. As pharmacy manager of a busy 24-hour Walgreens in Palm Desert, California, she is responsible for the safety and accuracy of the thousands of prescriptions th
week.

"There's so much stress," Jerominski said. "You're not only running to the dri[redacted] front, to the vaccination station to give a vaccination, then to the phone. ... It's almost impossible for any human to keep that momentum day in and out."

It wasn't always that way. When she began working as a pharmacist 13 years ago, it was a very different environment, Jerominski said. There were more staff members and more time to counsel patients about their medications. These days, she is exhausted and often overwhelmed, worried about making a mistake when someone's health is on the line. She is far from alone.

Jerominski is one of an estimated 155,000 pharmacists working at chain drugstores who, over the past decade, have found themselves pushed to do more with less. They're working faster, filling more orders and juggling a wider range of tasks with fewer staff members at a pace that many say is unsustainable and jeopardizes patient safety. Now Covid-19 vaccinations are raising new concerns about what will happen if they aren't given enough additional support for yet another responsibility.

NBC News spoke to 31 retail pharmacists and pharmacy technicians in 15 states. From 12-hour shifts so busy they don't have time to go to the bathroom or eat to crying in their cars every day after work or lying awake at night worrying about mistakes they might have made while rushing, they described an industry of health care professionals at the breaking point.

Married pharmacists Shane and Marilyn Jerominski at their home in Indio, Calif., on Feb. 19, 2021.
Jenna Schoenefeld / NBC News

"The expectations they're having and the resources they're giving us just aren't matching up," said a CVS pharmacy technician in New York state. "We're going to have a fatal error somewhere because we're doing too many things at once."

Most pharmacists spoke anonymously out of fear of losing their jobs. Declining profit margins for pharmacies, corporate consolidation and an influx of new pharmacy school graduates in the past decade have led to stagnant or falling wages and fewer employment options, according to pharmacists, experts and recent studies.

The pressure and understaffing issues aren't new, as The New York Times reported last year. But they've worsened during the pandemic, pharmacists said, with new duties like Covid-19 testing, deep cleaning and now vaccinations stretching them even further.

"Pharmacists are being asked to do additional tasks and aren't necessarily receiving the assistance that they need from their employer," said Al Carter, executive director of the National Association of Boards of Pharmacy, a nonprofit that represents state pharmacy regulators. "That's a huge concern for pharmacists' well-being but also, more importantly, for patient safety."

The more overworked they are, the more likely they are to make errors, he said. Pharmacy errors can range from smaller mistakes, like miscounting the number of pills in a bottle, to potentially deadly ones, like missing a dangerous drug interaction. Working conditions and workplace pressures have led to "growing concerns from many state boards of pharmacy" about prescription errors, Carter said.

Walgreens and CVS, the country's largest pharmacy chains, were early government partners in the vaccine rollout. In statements to NBC News, they said that they are grateful for the work their pharmacy staffs have done during the pandemic and that they are hiring thousands of additional staff members to ensure that pharmacies have the support and resources to administer Covid-19 vaccine shots and provide the best care for patients. They and the trade group representing all chain drugstores also said technology improvements have freed pharmacists from many routine tasks in recent years, allowing them to focus on the safety and health of patients – their top priority.

CVS said the majority of stores giving Covid-19 vaccinations will do so through a dedicated team of pharmacists working only on vaccinations. In stores that don't, the company will provide additional staff support and limit the numbers of appointments.

Pharmacies have already begun to vaccinate around the country, but many pharmacists said they're worried about how much additional staffing they'll get to give vaccinations.

Marilyn and Shane Jerominski with their children, from left, Shaela, 7, Shia, 3, Shiloh, 5, and Shalyn, 9, at their home in Indio, Calif. Jenna Schoenefeld / NBC News

Jerominski's pharmacy began vaccinating last month. The vaccinations are going well, she said, but

other work has been piling up as she struggles to find time to do it all.

"Right now, it's just so crazy," she said during a shift break on her third day vaccinating. "Like, it's 1 o'clock, and I've done 14 Covid vaccines this morning, in between filling prescriptions. ... It's wonderful that we're doing this, and this is our duty. This is what we're supposed to be doing. But we need more help."

'Timed to the minute'

A pharmacist's job is far more than putting pills in bottles. Experts in drugs and medication management, they work everywhere from hospitals to cancer treatment centers and drugstores. They are among the best-educated health care professionals – they earn four-year clinical doctorates, which include rotations and often postgraduate residencies – and make median salaries of $128,000 a year. They are also some of the most trusted and accessible health care professionals in the country, according to the National Association of Chain Drug Stores.

The person who actually hands you your filled prescription at the counter may be a technician, not a pharmacist. Technicians are support staffers who run the cash register; fill, count and bag prescriptions; and unload inventory. They're entry-level employees who typically get on-the-job training or attend certificate programs and are paid a median $16 an hour.

Medication management services for customers can save billions in annual health care expenses, pharmacy groups estimate. Pharmacists said providing that advice is why many got into the business, yet they now have less opportunity to use those skills.

Marilyn Jerominski preparing to give flu vaccines in 2019. Courtesy Marilyn Jerominski

"I love being a pharmacist. I love being there for my patients," Jerominski said. "We used to be able to have time to actually have in-depth conversations about how the patient is doing."

But what might have once been five- to 10-minute patient consultations now typically happen in under a minute, she said. "It's not 'let us care for the patient.' It's 'how fast can we get the people in and out?'"

Walgreens, like many large pharmacy chains, gives pharmacists a range of metrics to meet and monitors the time they spend on various tasks, from calls to patients to prescriptions filled and vaccinations given per week. The chains, pharmacists said, began to push them more when profit margins started shrinking a little over a decade ago.

"Basically, your day is timed out by the minute – it's like the worst case of micromanaging you can imagine," said an Alabama pharmacist who has worked at Walgreens, CVS and Rite Aid in the past decade.

Walgreens didn't directly respond to questions about quotas and other metrics pharmacists must meet. In a statement, CVS said the metrics it uses to evaluate quality of service aren't unique, saying, "Over the past two years we've actually reduced those metrics by half, providing us with a clearer picture of what's working and where improvements may be needed."

In a statement, a spokesperson for Rite Aid said that the company believes the focus for pharmacists "should be on counseling customers for positive health outcomes" and that it has "created efficiencies and tools to open up pharmacists' time to consult and care for customers."

'The picture was grim'

While margins have tightened everywhere, pharmacists say the working conditions at some of the country's largest chain pharmacies are different from those at many independently owned pharmacies. Jerominski's husband, Shane, whom she met in pharmacy school, spent 10 years working at chain pharmacies and now manages an independent pharmacy. He was part of a class action lawsuit against one past employer, Walgreens, over wages and other issues. The suit was settled in 2014. He said his stress dropped markedly when he switched to working at an independent pharmacy.

"I see the difference. My level of autonomy is vastly different than Marilyn's, and the amount of help that I get is different than Marilyn," Shane said. There's still plenty of stress at his busy pharmacy, he said, but staffing is far better, and he isn't judged on the flurry of metrics he used to be beholden to. "I would never go back, honestly."

Recent surveys have borne out what pharmacists said has happened in their industry. In the 2019 National Pharmacist Workforce Study, which surveys thousands of pharmacists every five years, more than two-thirds of pharmacists said their workloads had risen in the past year. At retail chain pharmacies, 91 percent of pharmacists rated their workloads as "high" or "excessively high," the highest of any pharmacy type.

Shane Jerominski at work in his pharmacy. NBC News

Wages for a much greater proportion of pharmacists remained stagnant or fell compared to five years earlier, and the majority of pharmacists felt their job security and ability to find new work

had decreased in the previous year. Many pharmacists told NBC News that they worry that leaving current jobs would mean taking pay cuts, if they could find jobs at all.

The job market isn't in pharmacists' favor. There are twice as many pharmacy school graduates a year as there were 18 years ago, according to the American Association of Colleges of Pharmacy, yet the number of pharmacists jobs hasn't grown at the same pace. The Bureau of Labor Statistics predicts that the industry will shrink by 3 percent in the next decade.

A survey of pharmacists by the Vermont Pharmacy Board last fall, months into the pandemic, gave further insight into how working conditions at chain pharmacies compare to those at other pharmacies. Nearly 250 pharmacists from chain, independent and hospital pharmacies responded to the survey (and responded at rates roughly reflecting each category's share of Vermont pharmacists). They gave only retail chain pharmacies an "unfavorable rating" in any of the nine categories the survey examined. In fact, they gave the chains an "unfavorable rating" in every category, from patient safety to shift lengths and staffing.

Four in 5 retail chain pharmacists who responded to the Vermont survey said they worked more than 10 hours each shift; many reported that they arrived early or stayed late or never took meal breaks. Only 1 in 5 of the chain pharmacists said the number of pharmacists on duty was consistently adequate to provide safe patient care, and more than half said they had thought about leaving their jobs because of safety concerns.

Some of the conditions the board heard about "would be found unacceptable in a factory," such as pharmacists' developing kidney problems from skipping restroom breaks, said Gabriel Gilman, general counsel for the Vermont Office of Professional Regulation, which houses the state Pharmacy Board.

"The picture was grim," Gilman said. "We went into it expecting to find things that alarmed us. And we were alarmed at what we found even so."

'More like a fast food industry'

The industry is feeling the squeeze because of systemic financial factors, experts said. Steady profits are far less certain than they once were as pharmacies contend with declining profits for filled prescriptions and higher fees from middlemen who set drug prices nationally. And unlike most health care providers, pharmacists generally don't bill for their services. Instead, pharmacies make the vast majority of their income from dispensing prescriptions. The more prescriptions they dispense, the more money they make.

"Twenty years ago, you could make a decent living off the reimbursement of the drug and you had time to spend with patients," said Scott Knoer, CEO of the American Pharmacists Association. Knoer said that's no longer true and that all retail pharmacies have been struggling.

National chains have bought out regional ones, and independent pharmacies, which are about a third of retail pharmacies, are no longer as profitable as they once were. Independent pharmacy owners' average income fell by nearly half from 2013 to 2019, according to industry analyst Drug Channels Institute.

"The incentive design of pharmacy is: 'We pay you to fill prescriptions. We don't necessarily pay you to make people better,'" said Antonio Ciaccia, a consultant who has worked with the state of Ohio and the American Pharmacists Association on prescription drug pricing transparency and pharmacy payment reform. He said that's a bad model, especially combined with dwindling prescription profits.

"What you have is a race to the bottom, and at the bottom is an underresourced, heavily consolidated pharmacy marketplace that looks more like a fast food industry than a health care industry," he said.

There's no quick, easy fix. In Ohio, the state Medicaid program is trying a new payment model, which Ciaccia worked on, to allow pharmacists to bill insurers for clinical services.

Pharmacy trade groups and others are pushing for a national version of that model, giving pharmacists what's known as "provider status." A bipartisan federal bill to grant pharmacists the status was proposed repeatedly in the past decade, but it has yet to get a hearing.

While financial overhaul of the industry may be the ultimate goal for pharmacist groups, in the meantime, some states are also pushing to improve labor standards.

Marilyn Jerominski holds Shia, 3, at their home in Indio, Calif. Jerominski knew she wanted to be a pharmacist when she was a teenager but said she never dreamed her job would look like it does today.

Jenna Schoenefeld / NBC News

In recent years, states like California, Illinois and Virginia have created new rules, from capping shift lengths to mandating safe staffing levels and prohibiting excessive metrics. Vermont is working on new workplace condition rules based on its recent survey results.

About a third of all states now have regulations addressing pharmacy working conditions, according to the National Association of Boards of Pharmacy.

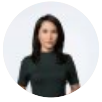
"There are challenges that are still huge concerns for boards of pharmacy ... and I don't see them going away any time soon," said Carter, the head of the association. "Especially with the pandemic, I see them getting worse."

For Marilyn Jerominski, it feels like the industry still has a long way to go. She knew she wanted to be a pharmacist when she was a sophomore in high school, but she said she never dreamed her job would look like it does today.

"You shouldn't wake up every day and feel disappointed in a profession where you go to school for seven-plus years," she said. "But how much more can you do? How much more can you do with less help? How much more can you do without making a mistake?"

Adiel Kaplan

Adiel Kaplan is a reporter with the NBC News Investigative Unit.



Vicky Nguyen

Vicky Nguyen is the senior consumer investigative correspondent for NBC News. See her reports on "TODAY," "Nightly News with Lester Holt," MSNBC and NBC News Now.

Mary Godie

Kit Ramgopal contributed.

Why Millennials Are Using Their Phones To Learn A Language In 3 Weeks

Babbel

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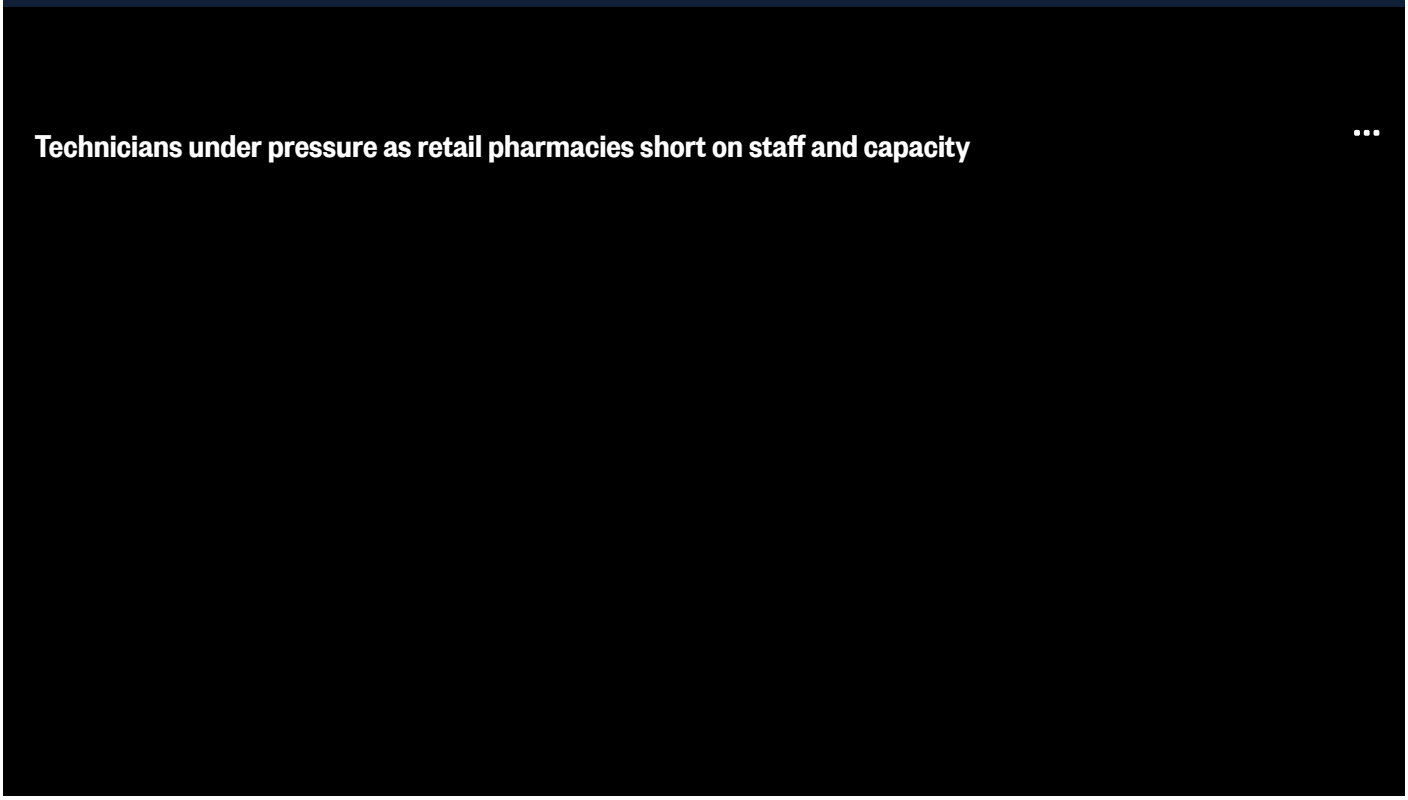
HEALTH NEWS

The latest worker shortage may affect your health: Pharmacies don't have enough staff to keep up with prescriptions

Pushed to the breaking point, pharmacy technicians are quitting in waves and stores are struggling to hire, leading to shorter hours, delayed prescriptions and risky mistakes.



Dec. 28, 2021, 6:31 PM KST / Updated Dec. 31, 2021, 5:45 AM KST

By Adiel Kaplan, Samantha Springer and Vicky Nguyen

Heidi Strehl worked as a pharmacy technician at a Rite Aid in the Pittsburgh suburbs for more than 16 years. She loved her customers, enjoyed her job and thought of her co-wo
fall, Strehl abruptly quit, walking out in the middle of a shift – one of many
technicians who are doing the same.

Most of the people behind pharmacy counters who count pills and fill medication bottles are pharmacy technicians, not pharmacists – low-wage workers in positions that don't require college degrees. Working in a pharmacy was always fast-paced, Strehl said, but in recent years the workload and stress had increased to unsustainable levels, while staffing and pay failed to keep up. During the coronavirus pandemic, the pace quickened further, especially once pharmacies began giving Covid-19 vaccine shots. Her store regularly ran behind on prescriptions, often with several hundred waiting to be filled each morning.

"It got to the point that it was just such an unsafe working environment, where you are being pulled a thousand different directions at any given time," she said. "You're far more likely to make a mistake and far less likely to catch it."

The last straws for her came in October. Strehl said she got an "insulting" 25-cent raise, bringing her to $15.08 an hour. A few days later, after yet another customer yelled at her over a delayed prescription, she had a panic attack in a corner of the pharmacy, crying and struggling to breathe while work continued around her. Then she grabbed her things, hugged her co-workers and walked out for the last time.

Heidi Strehl with her husband and children in 2020. Ashley Costanzo

"I always thought I would retire from that place," Strehl said. "But all of the parts of my job that I

truly enjoyed over the years had slowly just gone away."

Strehl is one of about 420,000 pharmacy technicians in the U.S. Even though they aren't highly paid – the median pay is $16.87 per hour – and often have no pre-employment medical training, they are vital to the health care system. They help pharmacists fill and check prescriptions and make sure patients get the right medication in the right amounts at the right time. Some even give vaccinations.

In recent months, many technicians have quit, saying they're being asked to do too much for too little pay, increasing the possibility that they will fill prescriptions improperly.

Employers, from major drugstore chains like Rite Aid, CVS and Walgreens to mom-and-pop pharmacies and even hospitals, are struggling to replace them. It's yet another of the labor shortages that have gripped the country this year. At many drugstores, the pharmacy staff members who remain are stretched thin. The shortage has led to dayslong waits for medication, shortened pharmacy hours and some prescription errors and vaccination mix-ups – like children receiving an adult Covid-19 vaccine shot instead of a flu shot – in a business sector in which delays and mistakes can have serious health consequences.

"Over the last five to six months, we've seen a spike in these conditions," said Al Carter, the executive director of the National Association of Boards of Pharmacy, a nonprofit organization that represents state pharmacy regulators. "In some states you have 60 or 70 pharmacies that are closing for days on end, because they don't have the appropriate staff."

A sign outside a CVS pharmacy Dec. 2 in Indianapolis. Staff shortages and a rush of vaccination-seeking customers are squeezing drugstores around the country. That has led to frazzled workers and even temporary pharmacy closures. Tom Murphy / AP file

While the shortage of technicians is being felt throughout the pharmacy industry, Carter said retail pharmacies, which have some of the lowest-paying positions in the industry, have been hit the hardest.

NBC News spoke to 22 retail pharmacy technicians in 16 states who recently quit or were considering quitting their jobs at major retail chains. Their experiences echoed Strehl's. Workload rose dramatically during the pandemic, but staffing levels didn't, with many stores instead losing workers and struggling to fill positions, compounding stress and burnout. All of the technicians said patient safety was their biggest concern.

"Being consistently overworked, underpaid, stressed out and behind, there's room for way too many mistakes," said Bella Brandon, who left her technician position at a CVS in Ohio in July without having another job lined up because she was so concerned about the potential for a deadly medication error.

"I had to get out of there as soon as possible," said Brandon, who now works in a hospital pharmacy with higher pay and more staff members. "It's not my job to play God."

Rite Aid, CVS and Walgreens all said they are proud of their staff members' work during the pandemic and are taking steps to support them, including major hiring efforts, often with signing bonuses. Rite Aid said it was temporarily closing most pharmacies an hour early to alleviate stress and help staff members catch up on work. Walgreens said that when staffing shortages affect stores, it may temporarily adjust store hours. CVS said its teams "remain flexible in meeting patients' needs" during the national workforce shortage.

Both Walgreens and CVS recently announced that they would increase technicians' starting salaries to $15 an hour or more. In a statement, the National Association of Chain Drug Stores lauded the work technicians do and encouraged consumers to make vaccination appointments ahead of time to help manage workflow in busy pharmacies.

'Not a cheeseburger'

Pharmacies can't run without technicians, who do the lion's share of work behind the counter, from counting pills to taking phone calls and ringing patients up. While anyone can become a

technician, filling prescriptions is a complex process, more than two dozen technicians and pharmacists said. It takes months of training about drug interactions, insurance claims and more to become skilled and efficient. Many states and employers require technicians to earn certifications after a certain number of months of work, as well.

Pharmacists, who have doctorates and make six-figure salaries, check technicians' work, consult with doctors, counsel patients and give vaccination shots. During the pandemic, many states began allowing technicians to give vaccination shots, as well, but everywhere, pharmacists and technicians said, the expectations for both jobs have been increasing.

"In an unsafe environment – because of the shortage of staff and increased workload that is being presented to that staff – your chance for error is going to increase," Carter said. "When you're dealing with medications, any prescription error could be life or death."

As the pressure has mounted, mistakes have increased, technicians said. They, their pharmacists or their patients are catching more miscounts of pills, mislabeled doses, even medications packaged in the wrong person's bag. Regulators are getting more complaints about prescription errors, as well, Carter said.

Recommended

HEALTH NEWS

CDC arrives in Ohio town to investigate health risks from toxic train derailment

In statements, CVS, Rite Aid and Walgreens all said that patient safety is their top priority and that they have systems to ensure that prescriptions are filled safely and accurately.

And then there are the vaccine mix-ups. In Texas, Indiana and Maryland, for example, patients have reported being given Covid-19 vaccine shots instead of flu shots, including several children who were given adult doses. Asked about the vaccination errors, Walgreens, which owns the stores where they happened, referred NBC News to its patient safety statement. Multiple technicians said they were afraid of moving so quickly and processing so many different kinds of vaccines that they might accidentally make the same mix-up.

Pharmacy working conditions have been a growing concern for regulators and pharmacy trade groups for years. The biggest concerns are at retail chain pharmacies, multiple state regulator surveys show. As Covid-19 vaccinations began in earnest last spring, pharmacists warned that without additional staffing, increasingly overworked and understaffed pharmacies would pose a threat to patient safety, NBC News reported in March.

The industry was already in crisis then. After years of declining profits and higher fees from middlemen who set drug prices nationally, pharmacies were increasingly pushing pharmacists and technicians to do more with less. In March, Carter said, he predicted that the conditions would get worse as the pandemic wore on.

Eight months later, technicians across the country said they have. Some said they often go full shifts without bathroom or meal breaks. A survey of pharmacy technicians from Ohio's pharmacy board this month revealed that 60 percent of the 2,560 respondents felt their workloads didn't allow them to provide for patients safely.

"It's not a cheeseburger we're talking about. ... This is life-sustaining medication in some cases, so you have to be able to focus on one thing at a time, not four things," said Kimberly Bailey Parry, a technician in Illinois who said she left her job at a CVS in a Target in August after 10 years to work for another pharmacy with better working conditions. "We were constantly being pulled in so many directions that it was only a matter of time before there was a major mistake."

Many technicians said there is little incentive to stay at most retail pharmacies when less stressful jobs are easily available for higher pay. They've gone to work at hospitals, pharmaceutical wholesalers and pet pharmacies or left the health care sector entirely.

Lea Polites, a Walgreens technician in New Jersey, said she is burned out and looking for another job. She showed NBC News local listings for a hotel clerk, a grocery store assistant manager and a cable sales representative, which all started with higher salaries than she was being paid as a technician. "If you want someone to take the job seriously, you might want to pay more than the

local grocery," she said. "They're driving all the good people away."

Major retail chains have made massive hiring pushes – CVS alone hired more than 10,000 pharmacy technicians in 2020. This year, it said, it is hiring thousands more. But overall, experts said, it's getting harder and harder to attract technicians throughout the industry.

The annual number of job openings for pharmacy technicians industrywide has grown by nearly 60 percent in the last five years, much of it since the pandemic began, according to the American Association of Colleges of Pharmacy, which tracks changes in the pharmacy labor market. Recent hiring pushes by large employers account for only part of the increase. Nearly 90 percent of independent retail pharmacies were struggling to find technicians, according to a survey last month of more than 300 independent pharmacy owners and managers by the National Community Pharmacists Association. Independent pharmacies make up one-third of all retail pharmacies.

'So burned out'

Jobs that start as entry-level positions, with limited upward mobility and often salary caps, don't encourage workers to build careers. The 22 technicians NBC News spoke to made $11.90 to $23 an hour, even though some, like Strehl, had more than a decade of experience.

Heidi Strehl started working for Rite Aid in 2005, when she was 19 years old. She worked at the same

store for more than 16 years. Courtesy Heidi Strehl

Scott Knoer, the chief executive of the American Pharmacists Association, previously led the Cleveland Clinic's pharmacy department, where he and colleagues examined turnover rates among the hospital network's staff members. They found that pharmacy technicians had far higher turnover rates than radiologic and nuclear medicine technologists and made about half their salaries. The hospital system classified each position similarly, but pharmacy technician was the only role of the three that didn't require an associate's degree.

"We have to pay pharmacy technicians more," Knoer said. "It's a rewarding job, but it's not an easy job. So it's not shocking that we have a shortage."

Pharmacy workers face an uphill battle in their push for better pay and working conditions. There are pharmacy trade associations and other industry groups, but unlike many other health care workers, few pharmacists and technicians are unionized. A group of pharmacists with large social media followings is pushing to change that, raising money through GoFundMe to create a national pharmacy workers union; it has raised $22,000 since the pandemic began.

There is recognition from established industry groups that things can't continue as they are. The National Association of Boards of Pharmacy, run by Carter, convened a task force last month to look at working conditions and how to address the patient safety issues they create. Some boards of pharmacy are changing rules to decrease workloads and provide more flexibility and worker protections.

A few regulators have turned to discipline. In the last two years, the Virginia and Oklahoma pharmacy boards have fined CVS hundreds of thousands of dollars over pharmacy working conditions, including inadequate staffing, saying they have led to prescription errors. CVS said that it agreed to the Oklahoma board's terms "to avoid the time and expense of a protracted hearing process," not as an admission of guilt, and that it disagreed with the board findings in Virginia, calling many of the staffing allegations in the board's report "inaccurate and outdated."

Heidi Strehl with her four sons in 2019. Ashley Costanzo

Many of the technicians who recently quit and spoke to NBC News said that despite the conditions, the work itself was something they loved. Strehl was one of them. But for people like her, who tried to build a career as a technician, industry reforms may be too little, too late.

“I was passionate about my job,” she said. “I never really thought that I would leave.”

Strehl’s husband, a baker, is providing the sole full-time income for their family of four sons and two dogs. She said they have enough money saved to get through the holidays without her paycheck, but she doesn’t know what’s next.

“I’m so burned out that I don’t know that I will ever try to do that again. At the same time, I really can’t see myself doing anything else,” Strehl said. “I called that place my home so many times. But the home that I knew is not the environment that exists.

“My heart is still there – I just can’t right now.”

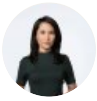
CORRECTION (Dec. 30, 2021, 3:45 p.m. ET): A previous version of this article incorrectly said there are no national organizations that represent pharmacy technicians. Those workers are represented by the American Association of Pharmacy Technicians, a national non-profit group.

Adiel Kaplan

Adiel Kaplan is a reporter with the NBC News Investigative Unit.

Samantha Springer

Samantha Springer is a researcher with the NBC News Investigative Unit.



Vicky Nguyen

Vicky Nguyen is the senior consumer investigative correspondent for NBC News. See her reports on "TODAY," "Nightly News with Lester Holt," MSNBC and NBC News Now.

Jason Calabretta and Jamie Nguyen contributed.

Why Millennials Are Using Their Phones To Learn A Language In 3 Weeks

Babbel

If you own a mouse, you will never turn off your computer again.

CombatSiege

40세 이상의 남자들을 위한 현실적인 게임

Raid Shadow Legends

www-pharmaciststeve-com-theyre-literally-making-us
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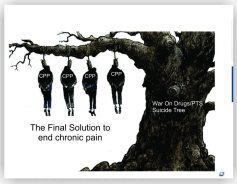
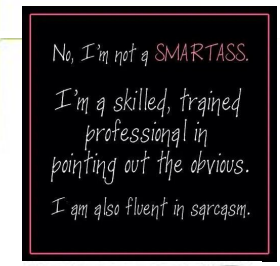
PHARMACIST STEVE



When I shut my mouth and turn to walk away, it doesn't mean you've won. It simply means your stupid ass isn't worth any more of my time.

"The moral test of a government is how it treats those who are at the dawn of life, the children; those who are in the twilight of life, the aged; and those who are in the shadow of life, the sick and the needy, and the handicapped." – Hubert Humphrey



"They're literally making us sick": Pharmacy workers describe conditions that sparked US walkouts

Posted on December 23, 2021 by Pharmaciststeve

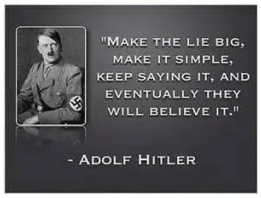
"They're literally making us sick": Pharmacy workers describe conditions that sparked US walkouts

https://www.wsws.org/en/articles/2021/12/23/cvsp-d23.html

Retail pharmacy workers conducted a nationwide walkout on Monday in the US, organized on social media, to protest worsening work conditions at large retail chains such as CVS, Walgreens and Walmart. As the hyper-infectious Omicron

DrugSense Drug War Clock

Current Time	10:22:21 P.M.
Federal Spent	$2,408,944,434
State Spent	$4,105,906,078
Total Spent	$6,514,850,512
All Drug Arrests	265,941
Cannabis Arrests	137,225
Imprisoned	1,730



Genocide in America updated 02/04/2016

Being Denied Meds – how to file complaints updated 11/12/2015

Being Denied Meds - how to f
complaints

passionate pachyderms

Pharmacist Steve

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variant continues to spread throughout the country, this much overlooked section of the health care industry is making its own demands for better working conditions, including patient safety, and an overdue increase in wages.

One pharmacist who requested to remain anonymous told the WSWS, "We work 12 hour shifts without technicians, we have no breaks and no lunch break as the drive-thru has to be open. We have not had a raise in four years." He emphasized the need for pharmacy technicians who "help take care of customers and type and count prescriptions, so if there is no tech, then the pharmacist has to try and do everything all while filling prescriptions accurately and giving COVID vaccinations."

He said the job "gave me so much stress that I developed heart arrhythmia and had to be on meds. They're literally making us sick."

Even before the pandemic began, these workers already faced chronic under staffing and low pay, circumstances that were only made worse during the pandemic.

Bled Tanoe, the pharmacist who started the popular #pizzaisnotworking hashtag and Facebook group, spoke to the World Socialist Web Site on the conditions facing pharmacists. "There is no shortage of pharmacists," she said, "but people are refusing to work in dangerous working conditions with high medical errors. There is a refusal to work in an environment that is detrimental to pharmacists and patients."

Tanoe used to be a retail pharmacist at Walgreens, but she left her job after numerous years of stress and abuse in the opening months of the pandemic. She described the mental, physical and emotional stress on pharmacists who are leaving the profession in droves. "It is a very dangerous situation that people don't realize. It's not just putting medicine in bottles; someone has to check you don't have an allergy, correct medication, the duration and everything are correct." She described that there have been many instances where patients "get flu vaccine instead of COVID vaccine, or even the wrong vaccine entirely."

Tanoe described the multiple responsibilities piled on pharmacists as similar to a pilot on a plane being "asked to serve drinks and take care of passengers while no one is running the plane." Pharmacists have to "make sure medications are correct, in the right doses, make sure there are no issues with allergies, etc."

The number of pharmacists nationwide who took part in the walkouts is not yet clear, but Tanoe noted that where pharmacy staff have not walked out, it was due to fear of retaliation by their employers, "not because they don't want to."

Such accounts are not uncommon. One worker on Twitter responded to a tweet by CVS Health's CEO, Karen Lynch, about the massive profits the company made in its third quarter, "Karen I've been a worker at CVS for 6 straight years. You all can report HUGE earnings but WON'T pass those earnings on to us techs who work SOLO 40+ hours a week and develop medical problems because of being overworked without 'enough hours' to hire more people. Help US instead."

In September, a pharmacist died of a heart attack on the floor of a CVS pharmacy after being told by a supervisor that she could not leave until another pharmacist arrived to relieve her two hours later. The hashtag #SheWaited has been used to bring attention to this senseless tragedy.

Such crippling conditions can contribute to pharmacists and pharmacy techs making dangerous errors while filling prescriptions. This led one pharmacist to write to the Texas Board of Pharmacy in April 2020: "I am a danger to the public working for CVS." In December 2018, an 85-year-old Florida woman died after two weeks when she was accidentally given a strong chemotherapy drug instead of her usual medication.

Dr. Shane Jerominski, the southern California pharmacist who first issued the call for Monday's walkouts, spoke with the World Socialist Web Site. "I tried to organize this as a show of solidarity, because we are working in unsafe environments and something has to give.

"It's hard to say how many walked out." explained Jerominski, "In the Palm Springs market, there were five stores closed. They have about 23 locations. They're all understaffed.

"A lot of technicians could get behind it. They felt that if they didn't show up that day, they can still operate. If the pharmacist doesn't show up, the pharmacy can't operate. Many pharmacists felt they couldn't do that to their patients."

Highlighting the brutal conditions facing pharmacy technicians, Jerominski noted,

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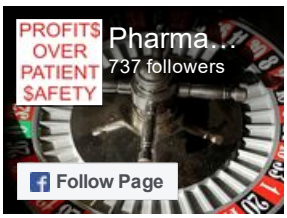

License to lie

"In the Palm Springs market, it's a cyclical market. Some technicians would be guaranteed 40 hours a week and then get flexed out in the summer."

Jerominski explained his personal motivation for fighting to organize pharmacy workers. In March of 2021, Jerominski and his wife, Marylin, began warning about the stresses that the coronavirus vaccination campaign would place on already overburdened pharmacists without additional support. "My wife and I were featured at NBC with Lester Holt. She's working at one of the busiest Walgreens in the area and now we're expected to vaccinate everybody. They started with one every 15 minutes, then three every 15 minutes, and they still had to fill all the regular prescriptions.

"We thought they were going to fire her for talking to the media. Corporate basically promised her the world, said she would get extra help, but never delivered. They are making it very difficult for her to try to get her to quit. They don't want to fire her. The media asked us to let them know if they fired her."

Jerominski's outspoken fight for the rights of pharmacy workers may have already resulted in retaliation against his independent pharmacy in Brawley, California. "I wanted to participate, I wanted my entire store closed. I had every intention of not being open as well on Monday at my location. On Friday—we're open Monday through Friday—I opened the pharmacy and the second patient was an inspector from the board of pharmacy who had received an anonymous complaint to inspect the pharmacy. Now I have to submit a lot of paperwork by December 24 to keep my license and I had to work through the strike.

"I've been a pharmacist for 15 years and I've never seen a Board of Pharmacy inspection until I started working for an independent. The first time was about four and a half years ago, about three months after I started working here. That inspection first was due to issues with the prior pharmacist."

Although it is unknown who filed this anonymous complaint, the timing is highly suspect. "Sitting on the California Board of Pharmacy are many middle-level managers of pharmacy chains," noted Jerominski, "I think I made someone irritated."

Jerominski remains determined to organize pharmacy workers for better conditions. "Pharmacists do have more power than they know. You can't have the pharmacy open without them."

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canarensis, on December 24, 2021 at 11:29 am said:

When I went to my (new) pharmacy a few days ago, there was a 1/2 hour wait just to drop off a scrip; the wait to pick up a filled scrip was over 2 hours. This was BEFORE all of the thousands of customers in my area who went to a local chain pharmacy discovered that Walgreens bought out the pharmacies and, instead of re-opening them as Walgreens (as originally claimed), closed them all with just a few days' notice.

I know that profits uber älles is the American way, but both customers & pharmacy staff are already having horrible health outcomes from stress & pharmacy mistakes; the pharmacy staffs are so overwhelmed they cannot help but make mistakes. It is going to get MUCH worse. I'm passing out little pamphlets to the hundreds in line with me to try & get customers to raise Hell; we can't exactly just go off our meds to punish the pharmacies, but maybe if we bombard both corporate offices & our senators & reps, ….?? I dunno; I'm desperate. I used to have a 5 minute trip to pick up my meds; now I have at least an hour round trip over one of the most dangerous stretches of road I've encountered in decades of driving.

My quickie little note (I added that first line b/c I have worked with the public many times & have a good idea of the abuse the pharmacy staffs are dealing with):

THIS INSANITY IS NOT THE PHARMACY STAFF'S FAULT!
I'm also a customer suffering from the lack of pharmacies & pharmacy staff. It is inconvenient for us, and also dangerous because overstressed & overworked staff will make mistakes; they can't help it. Their health is suffering as well! Please, write/email/call [your Senator/Rep], [relevant Corporate office], & the corporate offices of every other pharmacy in [your city/county]; they are ALL insanely overworked & understaffed.
Reply

thehigharts22, on December 23, 2021 at 5:25 pm said:

Best Regards to our vital pharmacy workers who have been so poorly treated…
Reply

Leave a Reply

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Overwhelmed, Overburdened Pharmacists Spend Less Time With Patients, Hurting Retail Pharmacy Business

Dec 23, 2021
Matthew Gibbs

The health of a pharmacy business is under attack from many directions, but retail pharmacies can take steps to alleviate some of this pressure to improve the health of their business.

There was a time, not too long ago, when an engaging consultation with your local pharmacist was a typical part of filling one's prescription medication. As recently as 2013, pharmacists spent an average of 2 hours each day counseling patients. There's a good chance they even knew their customers by name.

Anyone who has picked up a prescription in recent years has probably had an entirely different experience. Most of the time, you're lucky if the pharmacist lifts their head from behind the counter to make eye contact. Instructions about medication use are impersonal, delivered either via the cashier working the register or via an electronic keyboard with generic, pre-programmed questions.

It’s not that today’s pharmacists are uncaring or ambivalent. It’s simply a case of being overwhelmed, understaffed, and performing administrative tasks to remain “compliant” with insurance company requirements.

The administrative burdens facing today’s retail pharmacists are daunting, driven by several factors:

Increased requirements from third parties mean more time spent chasing down doctors for prior authorizations, reviewing formularies and engaging in a seemingly endless back and forth of phone calls and paperwork before a prescription can be filled.

Regulatory prohibitions levied by some state boards prevent pharmacists from offloading administrative activities to technicians, interns, or junior personnel.

In addition to the typical day-to-day prescription-filling activities—and all that those activities entail—pharmacists have now been asked to take on the role of active clinician-patient care as well.

In too many cases, the pharmacist has become a robotic order-taker with less time than ever to engage with patients. The business of the pharmacy and the health and wellbeing of the pharmacy’s patients suffer as a result.

Retail pharmacies can take steps to alleviate some of this burden and, at the same time, improve the health of their own businesses, which are constantly under competitive and economic pressures. Here’s how:

1. Lean Into Using More Tech Automation.

Sure, there have been improvements in the past 5 to 10 years in the way retail pharmacies deploy technology. The advent of electronic prescriptions, now extremely widespread, is one example. But the fact is, pharmacies are simply not fully embracing technology.

New platforms have the capability to streamline and automate many of the processes that engulf the time and attention of pharmacists. For example, electronic prior authorization systems can automatically engage the prescribing physician and complete the necessary processes before the script winds up in the pharmacist's hands. Connecting to EMR data systems and leveraging artificial intelligence can quickly reveal details about a patient's medical history relevant to the drugs they've been prescribed and streamline the process for securing approval.

On balance, the retail pharmacy industry is woefully behind in implementing the technology that can allow pharmacists to return their focus to quality of care.

2. Change the Paradigm by Going to Bat for Pharmacists.

Retail pharmacies need to go to bat for their pharmacists and take on both state boards and pharmacy benefit managers to create a more favorable working environment. As mentioned earlier, too many pharmacists are hamstrung by outdated, antiquated and, in some cases, nonsensical rules that dictate how much support they can access from technicians and interns and how they can be utilized in the pharmacy.

Pharmacists should be able to lean on their clinical capabilities to switch a simple prescription without having to track down physicians and chew up the precious time of the health care system. Chasing down payments and co-pays should be the purview of others in the ecosystem. It's incumbent on retail pharmacies to push for these types of changes.

3. Embrace an Evolving Clinical Role for Pharmacists.

The urgent push for vaccinations against COVID-19 converted pharmacists, many of whom may have been content to remain behind the counter, into a veritable army of immunizers. Retail pharmacies should continue to empower and enable pharmacists to deliver value-added clinical services like vaccinations, long after the hopeful conclusion of the pandemic. With necessary training, pharmacists can ultimately deepen the relationship with the patient by delivering more than just medication, cultivating greater trust and loyalty to the pharmacy.

The health of a pharmacy business is under attack from many directions. Ongoing reimbursement challenges and the emergence of specialist mail pharmacies are among the range of growing threats. Pharmacist burnout is up there, too. Empowering and enabling pharmacists to deliver the time, attention and enhanced quality of care patients crave will both preserve pharmacists' collective sanity and bolster the health of the business.

About the Author

Matthew Gibbs is the president of commercial markets at Capital Rx.

Related Videos

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SB372.pdf
Uploaded by: Jill Kapper
Position: UNF

Jill Kapper
221 Owings Gate Court
Owings Mills MD, 21117

UNFAVORABLE SB372
February 27, 2023

My name is Jill Kapper. I'm a lifelong resident of Maryland, an outspoken health freedom advocate and most importantly, a mother. I'm testifying today to oppose SB372 because it's offensive, unethical and a number of other things.

It's offensive because we're trying to remove parents from the equation when they're usually the ones responsible for their children to be capable of making these types of decisions in the first place. I'm wondering who's supposed to fill in that gap and why?

It's unethical because {if we're lucky} parents are advised to report to VAERS during an adverse reaction or when they believe their children may have been injured by vaccines. Well they couldn't possibly be aware of something that has purposely been hidden from them. What do ya know, another WIN for big pharma…all on the backs of our children.

We'd all agree that it's our responsibility to protect children. This should be obvious. Please take a step back to consider how damaging bills like this could be and work with us, rather than against us. Thank you for listening.

Jill Kapper

Emergency-Motion-for-Declaratory-Injunctive-Relief

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Position: UNF

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

WOMEN OF COLOR FOR EQUAL JUSTICE, et al.

Plaintiffs,

v.

THE CITY OF NEW YORK, MAYOR ERIC L. ADAMS, COMISSIONER ASHWIN VASAN, MD, PHD DEPARTMENT OF HEALTH AND MENTAL HYGIENE, DEPARTMENT OF EDUCATION, AND DOES 1-20

Defendants.

Case No: 22-3065

Emergency Motion

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS-APPELLANTS EMERGENCY MOTION FOR AN EXPEDITED APPEAL AND AN EMERGENCY DECLARATION AND INJUNCTION PENDING APPEAL

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Phone: 301-447-3600
www.woc4equaljustice.org

Attorney for Women of Color for Equal Justice, Plaintiffs and similarly situated

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I. PRELIMINARY STATEMENT

This emergency motion for declaratory and preliminary injunctive relief pursuant to the Declaratory Judgment Act (DJA) 28 U.S. Code § 2201 and §2202 is one of first impression that makes two facial constitutional challenges to the "authority" of the City of New York ("City") Health Commissioner to issue nine (9) Covid-19 vaccine orders (the "Vaccine Orders"[1]) (Exhibit 1) mandating City employees to take the Covid-19 vaccine or be placed on indeterminate involuntary leave without pay (ILWOP). The two challenges asks this Court to find that the holding in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) regarding compulsory vaccination has been overturned by the passage of the OSH Act and that the rational basis test in *Employment Division, Department of Human Resources of Oregon v. Smith* 494 U.S. 872 (1990) is inapplicable because the right to refuse vaccines is no longer a crime[2] and is a fundamental right under the First Amendment Free Exercise and Due Process Clauses subject to strict scrutiny, which no vaccine can meet.

The first challenge is that the Vaccine Orders (on their face) mandate the use of the Covid-19 vaccine as "safety method" when neither vaccines nor any

[1] While the New York City Mayor announced that he will make the Vaccine Orders optional effective on February 10, 2023, the declaration and injunction is still needed because the City is still enforcing it police power to prevent City workers placed in IILWOP from automatically returning to their jobs and to deny City workers backpay due because of the void orders.

[2] See Sherbert v. Verner, 374 U.S. 398, 403-404 (1963) which held that ineligibility for unemployment benefits, based solely on a refusal to violate the Sabbath, has been analogized to a fine imposed on Sabbath worship that violates the First Amendment Free Exercise Clause – the distinction between Sherbert and Smith facts are that the religious practice in question in *Smith* was a crime and the religious practice of observing the Seventh-Day Sabbath from sun down Friday to sun down Saturday according to the Fourth Commandment is in the Bible and Torah has never been a crime.

immunization has ever been approved as "safety methods" by the Occupational Safety and Health Administration (OSHA). Also, vaccines are incapable of meeting Occupational Safety and Health Act (OSH Act) minimum safety standards for preventing the transmission of airborne hazards, including airborne communicable disease like Covid-19. Because the use of the Covid-19 vaccine falls below OSHA minimum standards, neither the City's Health Commissioner nor any employer has authority to mandate any employee or persons in places of business to submit to the illegal Covid-19 vaccine. While the City, along with many public and private employers mandating vaccines as a condition or pre-condition of employment along with legal organizations,[3] believe they have the constitutional right to mandate employees to submit to the illegal Covid-19 vaccine now on in the future based on the holding in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), that "belief" is erroneous. The *Jacobson* decision was overturned over 50-years ago when Congress enacted the 1970 OSH Act minimum safety standards - as was instructed by the Supreme Court in *Jacobson*[4] and later confirmed *City of Boerne v. Flores*, 521 U.S. 507 (1997)[5] - abrogating the police power of states and municipalities to criminalize or sanction in any way individuals who exercise their fundamental right to refuse

[3] See American Bar Association, October 21,2021 – "Not Breaking News: Mandatory Vaccination Has Been Constitutional for Over a Century" @ https://www.americanbar.org/groups/litigation/committees/mass-torts/articles/2021/winter2022-not-breaking-news-mandatory-vaccination-has-been-constitutional-for-over-a-century/

[4] Id. at 25.

[5] Held Congress ""Congress certainly can enact legislation enforcing the constitutional right to the free exercise of religion,..."

vaccines. The OSHA Act ban on sanctioning employees also applies to private employers, and in 1992 the Supreme Court held that private employers are prevented from making any unauthorized safety method a condition or pre-condition of employment.[6]

Because the City and many employers around the country are unconscionably enforcing the *Jacobson* and will in the future, Plaintiffs (and all similarly situated employees for which Plaintiffs have requested conditional certification)[7] seek an immediate emergency DJA declaration of rights issued from this Court declaring that any vaccine mandate or vaccine condition for pre- or post-employment by any employer violates federal law and is unconstitutionally void and illegal subjecting all employers to constitutional tort[8] private right of actions for monetary damages and injunctive relief as expressly permitted under the OSH Act 29 U.S.C. Section 11(c). See generally *Nary v. Haitian Refugee Center, Inc*, 498 U.S. 479, 493 (1991)[9]

Plaintiffs second facial constitutional challenge is pursuant to Section 1983 as right of action for the City's continued enforcement of the illegal Vaccine Orders and new orders of February 6 and 8, 2023, under color of law, which now is

[6] Gade v. National Solid Wastes Management Assn., 505 U.S. 88, 108 (1992)
[7] See Exhibit 35 - Plaintiffs Motion for declaratory and injunctive relief to the Eastern District Court included a motion for class certification.
[8] See Carey v. Piphus, 435 U.S. 247, 253 (1979) ("The legislative history of [Section] 1983 . . . demonstrates that it was intended to create a species of tort liability in favor of persons who are deprived of rights, privileges, or immunities secured to them by the Constitution.")
[9] (held: "Because the administrative appeals process does not address the kind of ….. constitutional claims respondents bring in this action, limiting judicial review of these claims to the procedures set forth in § 210(e) is not contemplated by the language of that provision.")

preventing them from returning to work without having to first re-apply for jobs they were not terminated from and waive their claims to backpay and damages. The new employment conditions are also deprivations caused by their exercise of their Free Exercise right to refuse to take the illegal Covid-19 vaccine[10] and deprives them of their right to immediately return to work unvaccinated in violation of the OSH Act 29 U.S.C §669 Section 20(a)(5) and §660, Section 11(c)(1). The Vaccine Orders expressly state that all unvaccinated City employees "must be excluded from premises at which they work beginning November 1, 2021" for failing to provide proof of Covid-19 vaccination (See Exhibit 1) While Plaintiffs have not been legally terminated from their jobs because the New York City Civil Service laws prevent their termination,[11] Plaintiffs have been placed on indeterminate involuntary leave of without pay (ILWOP) denied healthcare, unemployment and retirement benefits and are prevented from returning to their jobs without cost which is their absolute right due to the City's continued enforcement of the illegal Vaccine Orders.

Additionally, Plaintiffs have been subjected to ongoing religious harassment by the City because the City continues to send them letters attempting to coerce

[10] *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990) (Held: A competent person has a liberty interest under the Due Process Clause in refusing unwanted medical treatment. Citing *Jacobson v. Massachusetts*, 197 U. S. 11 1905.

[11] City's progressive discipline law only permits termination if an employee is guilty of a violation of either New York City Education Law §3020, for tenured teachers, New York City Administrative Code §16-101 for Sanitation employees; or New York City Civil Service Law §75 for all City employees.

them to give up their religious beliefs in exchange for their jobs in violation of the New York State Human Rights Law which prohibits employers from engaging in coercive tactics. (NYCHRL §8-107). (See Exhibits 33) This "quid pro quo" harassment continues wherein on Monday, February 6 and 8, 2023 the City's Mayor Adams announced that Plaintiffs will have to reapply for their jobs and waive their right to backpay and all damages, which are additional unconstitutional burdens on their fundamental right to return to their jobs. (See Exhibits 3 & 4) This is outrageous and a "shock to the conscience" *Rosales-Mireles v. United States*, 138 S. Ct. 1897, 201 L.Ed.2d 376 (2018) because the 1st Circuit already held in 1994 that backpay can be awarded for wrongful discharge under OSHA.[12]

Congresses intent to overturn the harsh outcomes from the *Jacobson* decision - as seen in this case - is expressed in the language of the OSH Act Section 20(a) which protects all employees' fundamental Free Exercise right to refuse immunization, which is a fundamental right first recognized by the *Jacobson* court and re-iterated by the Supreme Court in *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 262 (1990) which held that all competent adults have the right to refuse medical treatment regardless of their religious beliefs.

[12] See *Reich v. Cambridgeport Air Systems, Inc*. 26 F. 3d 1187, 1190-1191 (1st Cir. 1994)

While Plaintiffs have met their burden of proof for equitable relief, on November 18, 2022, the New York Eastern District Court denied Plaintiffs motions for preliminary injunction and declaratory relief based on two (2) errors, which are reviewable de novo and include, an error of law regarding private rights of action under the OSH Act and error regarding the proper legal standard applicable to Plaintiffs request for relief under the DJA.(Exhibit 5) The district court incorrectly concluded that the OSH Act does not provide a private right of action, which precluded application of the less strenuous standard under FRCP §57. The OSH Act expressly permits private rights of action and equitable relief is permissible under the DJA when there is ongoing violations of federal law and constitutional rights that can only be stopped through a prospective injunction and declaration of rights.[13]

Based the ongoing and imminent acts of the City, DJA relief is the only way to halt theses egregious violations by the City and employers around the country. This Court should grant emergency equitable relief as detailed in the proposed orders supporting this motion. Since the Pandemic emergency is over, an injunction, until this Court can resolve the appeal on an expedited basis, would not disrupt the status quo by allowing Plaintiffs and similarly situated employees

[13] See *Free Enterprise Fund v. Public Company Accounting Oversight Bd.*, 561 U. S. 477 (2010) (Sotomayor, J. dissenting –"We have thus long entertained suits in which a party seeks prospective equitable protection from an injurious and preempted state law without regard to whether the federal statute at issue itself provided a right to bring an action...").

robbed of such a precious fundamental right to immediately go back to their jobs and immediately receive backpay to recover from the horrific financial and mental damage caused by the tortuous acts of the City, which no amount of money can adequately compensate.

II. BACKGROUND

A. Factual Background

On March 11, 2020, the World Health Organization declared the infectious airborne Covid-19 virus a Global Pandemic. (Exhibit 6) According to the CDC, the principal mode by which people are infected with the virus is through exposure to respiratory fluids carrying infectious virus, which exposure occurs in three principal ways: (1) inhalation of very fine respiratory droplets and aerosol particles (e.g., quiet breathing, speaking, singing, exercise, coughing, sneezing) in the form of droplets across a spectrum of sizes, (2) deposition of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays, and (3) touching mucous membranes with hands that have been soiled with virus on them. (Exhibit 7)

For decades OSHA has had minimum health and safety standards that cover all infectious diseases, specifically airborne infectious diseases. The list of minimum approved safety methods for respiratory disease exclusively include the General Respiratory Standard at 29 CFR §1910.132, the Personal Protective Equipment

standard at 29 CFR §1910.132, the Respiratory Protection standard at 29 CFR §1910.134 and the General duty Clause of the OSH Act 29 U.S.C. §654 (collectively hereinafter "Respiratory Standards"). (Exhibit 8)

In 2009, the World Health Organization declared H1N1 a "global pandemic" and OSHA did not add vaccines to the list of approved safety methods.[14] (Exhibit 9) In 2015, OSHA Published, along with the CDC Hospital Respiratory Protection Program Toolkit (which applies to any employer), which outlines the effectiveness of various "respirators" that are required under the OSHA Respiratory regulations, and the publication notes that Powered Air Purifying Respirators (PAPR[15]) and/or N95 Respirator are the best of all respirators for shielding Employees from hazardous airborne viruses because they provide 99.97% effective. (Exhibit 9A, and Exhibit 10, Affidavit of OSHA Expert Hygienist)

OSHA Respiratory regulations also mandate employers to provide "remote work from home" as a safety method when an employer cannot remove an airborne hazard from the workplace atmosphere. (Exhibit 10) Expert cardiologist responsible for OSHA compliance, Dr. Baxter Montgomery, states that "vaccines are a medical treatment" and are not a safety method that shields workers from any airborne hazard

[14] See WHO video at https://www.youtube.com/watch?v=10Nfk0zcTAk and Exhibit 17 and See affidavit of Bruce Miller at Exhibit 10)

[15] The PAPR does not require the extensive OSHA medical approval and extensive fit testing "process" required under the OSHA Respiratory standard to utilize.

and the vaccine cannot remove viral airborne hazardous from the (Exhibit 11), which all OSHA respiratory safety methods must accomplish to become an authorized safety method pursuant to the regulations in 29 CFR §1910.134. (Exhibit 8)

During the 2020 Covid Pandemic, OSHA published guidelines specific to K-12 schools that mandates schools to follow the OSHA Respiratory Standards, including remote work. (Exhibit 12)

The New York State Department of Labor through its New York Public Employee Safety and Health (PESH) Bureau has an OSHA approved State Plan that expressly states that all New York employers including municipal employers are required to comply with the OSHA Respiratory Standards. (Exhibit 13)

One month after the Covid-19 Pandemic was declared in March 2020, the Ford Motor Company announced that it was increasing the manufacture of Powered Air Purifying Respirators (PAPRs) and N95 Respirators compliant with the OSH Respiratory Standards. (Exhibit 14) On March 27, 2020, the Federal Government passed the CARES Act and issued over $1.4 Billion to the City of New York for Covid-19 expenses, and the CDC provided an additional $25.1 million to the City specifically to assist the City with compliance with OSHA Respiratory Standards. (Exhibit 15)

On May 29, 2020, the Office of the Solicitor for OSHA issued a Response to an Emergency Petition declaring, in summary, that it was not "necessary" for OSHA to issue any Covid-19 related Emergency Temporary Standards (ETS 1920.502), specifically because the existing Respiratory Standards where sufficient for employers to comply with in order to manage the Covid-19 pandemic. (Exhibit 16)

Neither of the OSHA Emergency Temporary Standards issued in June 2021 and in November 2021 mandated employees to take the Covid-19 or lose their jobs nor authorized employers to terminate employees or place them on leave without pay for refusing to submit to the Covid-19 vaccine. (Exhibits 17)

Nevertheless, between July 21, 2021 and December 13, 2002, the City issued the Vaccine Orders that applied to City controlled "workplaces", public accommodations and private workplaces mandating that all City employees, and persons in public businesses and private sector workplaces to provide proof of Covid-19 vaccination and private employers would be fined for non-compliance. (Exhibit 1)

Any City employee who desired to be exempted from the Vaccine Orders was required to first submit to the City through an electronic portal a religious exemption request that required them to disclose their religious affiliation or church membership, provide a detailed explanation of their religious practices and/or

beliefs, and the City required a letter from a clergy before their request would be considered by the City for an exemption, which itself is a federal violation.[16] (Exhibits 18- 30 Affidavits of Plaintiffs.)

All Plaintiffs requested exemptions from the Vaccine Orders on religious grounds were denied the exemption requests. (Exhibits 18-30) On December 20, 2021 the New York City Law Department Office of the Corporate Counsel issued a legal memorandum titled "Guidance on Accommodations for Workers" instructing private employers that they could deny requests for religious exemptions from the Vaccine Orders based on the EEOC "undue burden" standard. (Exhibit 31)

The City refused to allow "remote work" for Plaintiffs who were already working "remote" and denied "remote work" to those who requested it with their request for exemption. (Exhibits 22 & 26) After City employees were denied vaccine exemptions, they were locked out their jobs instructed not to return to any City building and they were placed on indefinite involuntary leave without pay (ILWOP) and denied health insurance, retirement and unemployment benefits and the right to work. (Exhibits 18-30)

[16] See *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 204 L.Ed.2d 978 (2019), Footnote 11 "Congress has dictated that 'no person shall be compelled to disclose information relative to his religious beliefs or to membership in a religious body...."

Many Employees received letters stating that they were "terminated" when not one City employee who refused the vaccine received a formal "misconduct charge" for termination required by the City's Civil Servant progressive discipline laws.[17] (Exhibit 28)

According to the City's former Mayor DeBlasio in a New York Times report, approximately 12,000, or less than 5% of all City employees requested exemptions from the Covid-19 Vaccine Orders based on religious grounds. (Exhibit 32)

For the last year, Plaintiffs have been subjected to harassing and coercive tactics by the City to coerce them to go against their religious beliefs by promising their jobs and benefits in exchange for taking the vaccine. This "starve them out" tactic caused thousands who once stood for their faith to go against their God and take the illegal jab when they ran out of money. (Exhibit 30) Now those still standing, some of which are suffering abject poverty because "food banks" have refused them are demanded to re-apply for their jobs and waive their backpay claims. (Exhibit 3, 4, 33)

[17] City employees can only be terminated after filing of charges and progressive discipline pursuant either to - New York City Education Law §3020 for tenured teachers, New York City Administrative Code §16-101 for Sanitation employees and New York City Civil Service Law §75, which applies to all City employees.

B. Historical Background - OSHA Overruled Jacobson 50 Years Ago

1. The OSH Act Expressly Abrogated State & Municipal Police Power to Criminalize the Religious Practice of Refusing Vaccines

The 10th Amendment grants states and local governments[18] "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." Consistent with this Federalist Principal, it was held in *Jacobson v. Massachusetts,* 197 U. S. 11 (1905) that states not only have the general police power to enact criminal laws, but specifically states can enact laws that criminalize religious activity ordinarily protected as a fundamental right by First Amendment Free Exercise Clause. When the *Jacobson* Court upheld the State of Massachusetts criminal prosecution of Mr. Jacobson for refusing the smallpox vaccine as a religious practice, that landmark decision became the foundation for the legal principle that religious practices can be criminalized, specifically the religious practice of refraining from vaccines,[19] so long as the criminal law is "reasonable" for the protection of public health and safety. [20] However, the *Jacobson* decision also provided a roadmap for Congress

[18] See Dillion Rule - *Clinton v. Cedar Rapids & M. R. R. Co.*, 24 Iowa 455 (1868) – adopted by the U.S. Supreme Court in *Hunter v. City of Pittsburgh*, 207 U.S. 161 (1907), held in summary that local governments are considered an extension of the state and power is distributed to those local governments according to the state constitution.
[19] Other religious practices like bigamy, smoking peyote and working on Sunday have been criminalized see *Braunfeld v. Brown, 366 U.S. 599 (1961) 1959* - Pennsylvania criminal statute which forbade the retail sale on Sundays of commodities and other specified commodities.
[20] See *Jacobson v. Massachusetts*, 197 U.S. 11, 13 & 26 (1905) - "Jacobson was prosecuted against by a criminal complaint in one of the inferior courts of Massachusetts…. that subjected him to a fine or imprisonment for neglecting or refusing to submit to vaccination…."

to legislate to limit state police power to criminally punish and fine citizens for their religious practices as stated below:

> "it is for the **legislature**, and not the courts, to determine in the first instance whether **vaccination is or is not the best mode for the prevention** of smallpox and the protection of the public health." Id. at 197. (Emphasis added)
>
> A local enactment or regulation, even if based on the acknowledged **police powers** of a State, **must always yield in case of conflict with the exercise by the General Government** of any power it possesses under the Constitution, or with any right which that instrument gives or secures. (Emphasis added)

65 years later, Congress did overturn the *Jacobson* decision on three (3) grounds when, it passed, through its Constitutional power under Article 1, Section 8 of the Commerce Clause, the Occupational Safety & Health Act of 1970 (OSH Act) (Exhibit 34) creating the federal Occupation Safety and Health Administration (OSHA). First, the OSH Act limited states police power to regulate in the area of health and safety specifically in places of business and workplaces affecting interstate commerce and reserved exclusive authority to OSHA's Secretary through 29 U.S.C. §655 Section 6(b)(6)(iii) to promulgate minimum health and safety standards and to determine the "practices, means, **methods**, operations, and processes" to meet the minimum standards. 29 U.S.C. 651 Section 2(b)(5). Specifically, the Secretary was charged "to supply a nationwide floor of minimally necessary safeguards" that federal, state and private employers and

places of business are mandated to meet for public health and safety. 29 U.S.C. § 651(b) see *Solus Indus. Innovations, LLC v. Superior Court of Orange Cnty*., 410 P.3d 32, 228 (Cal. 2018). The OSH Act was enacted "to address the problem of uneven and inadequate state protection of employee health and safety" and to "establish a nationwide 'floor' of minimally necessary safeguards". *United Air Lines, Inc. v. Occupational Safety & Health Appeals Bd*., 32 Cal.3d 762, 772, 654 P.2d 157 (1982)

The constitutionality of this exclusive authority to set minimum standards mirrors Congresses power to set "minimum wage standards" in the Fair Labor Standards Act 29 U.S.C.A. §201 et seq. (FLSA) passed years earlier in 1933. See *Opp. Cotton Mills v. Administrator of Wage and Hour Division of Department of Labor*, 312 U.S. 657, 61 S.Ct. 524 (1941). The Supreme Court made clear in *City of Boerne v. Flores*, 521 U.S. 507, (1997), that "Congress can certainly enact legislation……. enforcing the constitutional right to the free exercise of religion."

While 29 U.S.C. §667 of the OSH Act expressly reserved to states the right to assume authority to promulgate new "higher" standards for which OSHA standards already exist, municipalities do not have the right to regulate below the "minimum standards as expressed in 29 U.S.C. 667 Section 18 as follows:

> (b) Any State which, at any time, desires to assume responsibility for development and enforcement therein of occupational safety and health

> standards ……..shall submit a State plan for the development of such standards and their enforcement.
>
> (c) The Secretary shall approve the plan submitted by a State under subsection (b), or any modification thereof, if such plan in his judgement --
> (2) provides for the development and enforcement of safety and health standards relating to one or more safety or health issues, **which standards (and the enforcement of which standards) are or will be at least as effective in providing safe and healthful employment and places of employment as the standards promulgated under section 6** which relate to the same issues, … (Emphasis added)

Both the U.S. Supreme Court in *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88 (1992) and this Second Circuit in *Steel Inst. of N.Y. v. City of N.Y.,* No. 12-276 (2nd. Cir. 2013) declared, in summary, that municipalities cannot regulate outside the express authority provided by the OSH Act.

While all vaccines obtain federal approval from the Food & Drug Administration (FDA), the 1938 Federal Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. § 301 et seq., only grants the FDA authority to regulate all "drugs" and "devices, " which include any "articles (other than food) intended to affect the structure or any function of the body," as well as any components of such articles. Id. § 321(g)(1)(C)- (D), (h)(3) (Emphasis added). The FDA does not have authority to regulate methods to be used to provide health and safety in physical places of business and workplaces. Neither does FDA approval of any vaccine, nor does CDC recommendation that the Covid-19 vaccine is "safe and effective", automatically make any vaccine an OSHA approved "safety method."

Moreover the OSH Act does not authorize the Secretary nor employers regulated by the Act to prescribe "medical treatments" to eliminate workplace hazards. The prescribing of vaccine medical treatments is exclusively reserved to physicians and licensed healthcare workers in the 50 states. It is a felony in New York for any unauthorized person to prescribe a "medical treatment". See New York Education Law §6520& §6521 and §6512

2. The OSH Act Consensus Requirement Further Limited State Police Power

Second, Congresses intent to overturn *Jacobson* is manifested by the fact that Section 6(a)&(b) of the OSHA Act requires the OSHA Secretary (when promulgating or modifying standards) to seek consensus on standards with other national organizations including, State or political subdivisions, See *Warren Tech., Inc. v. Ul LLC*, 962 F.3d 1324 (11th Cir. 2020) which must be "based upon research, demonstrations, experiments, and such other information as may be appropriate…." and must seek the "attainment of the highest degree of health and safety protection for the employee, and other considerations shall be the latest available scientific data in the field".

3. OSHA's Respiratory Standards Made Vaccines Unnecessary

Finally, *Jacobson* was overturned by Congress when the OSH Act Respiratory standards did not list vaccines as an approved "safety method." To

specifically address airborne hazards, OSHA only approved the specific methods in the list of Respiratory Standards, that include the OSHA General Duty Clause 29 U.S.C. §654 Section 5, which mandates employers to eliminate any known hazard in the workplace through engineer and administrative methods.

These approved safety methods have not changed despite the number of global pandemics involving hazardous respiratory agents, including the 2009 H1N1 Global Pandemic[21], and other infectious diseases for which OSHA has established directives, including SARS, MRSA, Zika, Pandemic Influenza, Measles, and Ebola. (See Exhibit 8)

The primary objective of the OSHA Respiratory Standards is to implement "practices, means, methods, operations, or processes" that, at minimum, either: 1) remove hazardous airborne contaminations from the atmosphere of a workplace and/or 2.) prevent employee exposure to known airborne contaminates in the workplace atmosphere. 29 CFR 1910.132 If a safety method does not meet these two objectives the method cannot meet the minimum safety method standard. Employers are obligated to remove "hazards" not people under the General Duty clause.

[21] In 2009 the World Health Organization declared H1N1 a global pandemic – See https://www.youtube.com/watch?v=10Nfk0zcTAk&t=38s

According to medical expert Dr. Baxter Montgomery, who also practices Biblical Plant-Based Lifestyle Medicine[22], vaccines are a "medical treatment" and are incapable of removing airborne contaminates from the air and shielding employees from exposure to airborne contaminants. (Exhibit 34). OSHA expert and Certified Hygienist, Bruce Miller, explains that the OSHA authorized respirators, specifically the Powered Air Purifying Respirators (PAPR) are 99.97% effective at shielding employees from exposure to any airborne hazard, which is the highest level of effectiveness rendering vaccines unnecessary. (See Exhibit 35)

III. STANDARD OF REVIEW

A district court's denial of a preliminary injunction is reviewed for abuse of discretion but legal conclusions are reviewed de novo, if "(1) it bases its decision on an error of law or uses the wrong legal standard; or (2) it bases its decision on a clearly erroneous factual finding… " *Klipsch Grp., Inc. v. ePRO E-Commerce Ltd.* , 880 F.3d 620, 627 (2d Cir. 2018)

IV. DECLARATORY JUDGMENT ACTION STANDARD OF REVIEW

For a court to issue a declaratory judgment, the Supreme Court has " required that the dispute be 'definite and concrete, touching the legal relations of parties

[22] Biblical Plant-Based Lifestyle Medicine is the evidenced based practice of prescribing plant and herb food as medicine consistent with the instructions in Genesis vers 1:29, and 3:18 along with lifestyle interventions, including exercise, rest, natural sunshine, fresh air, clean water, hygiene practices and various forms of fasting to prevent, treat and even reverse chronic and communicable disease including Covid. See Scientific evidence behind THE TEN LAWS of Plant-Based Lifestyle Medicine - https://hbcuplantbasedlifestyle.com/THE-TEN-LAWS-of-Lifestyle-Medicine-Scientific-Evidence.pdf

having adverse legal interests'; and that it be 'real and substantial' . . . .which calls for specific relief through a degree of conclusive character…" *MedImmune, Inc. v. Genentech, Inc*., 549 U.S. 118, 127 (2007) (internal citations omitted). Whether the City or any employer has the constitutional right to mandate vaccination as a condition of employment and whether employees and persons entering places of business affecting interstate commerce have the right to refuse any vaccination requirement are two of many ongoing controversies raised by this case that needs a DJA determination by this Court.

V. ARGUEMENT

A. OSH Act Legalized The Fundamental Right To Refuse Vaccines

The OSHA Act legalized the fundamental right of competent adults to refuse vaccines on religious grounds by preventing all sanctions while also providing employees a private right of action when they are discharged for exercising that right. The Supreme Court in *Armstrong v. Exceptional Child Center*, Inc., 575 U.S. 320, 332 (2015) held "that a private right of action under federal law is not created by mere implication, but must be "unambiguously conferred." (citing *Gonzaga* Univ. v Doe, 536 U.S. 273, 283 (2002). The task of the court "is limited solely to determining whether Congress intended to create the private right of action." *Touche Ross Co v. Redington*, 442 U.S. 560, 568, (1979).

Congresses intent to protect employees right to refuse vaccination is unambiguously expressed in OSH Act at 29 U.S.C. §20(a)(5) and §11(c)(1) as follows:

> **Nothing in this or any other provision of this Act** shall be **deemed to authorize or require** medical examination, **immunization**, or treatment **for those who object thereto on religious grounds**, except where such is necessary for the protection of the health or safety of others. See §20(a)(5)[23] (Hereinafter the "Automatic Right to Refuse Vaccines")
>
> No **person shall discharge any employee**……because of the exercise by such employee ……..of **any right afforded by this Act**. §11(c)(1) (Emphasis added)

Section 11(c)(1) essentially provides all employees the right to remain unvaccinated and work by prohibiting any person from discharging an employee for exercising their fundamental right to refuse any vaccine or immunization. The U.S. Supreme Courte expressly stated in *Gade* that employers are prohibited from mandating unauthorized safety methods as a "pre-condition to employment". See *Gade at* 108.

B. The OSH Act Provides An Expressed Right of Action For Constitutional Tortuous Wrongful Discharge

Congress also made crystal clear that employees have the right to maintain a private right of action for a constitutional torts against "any person" who

[23] Because vaccines are incapable of removing any airborne hazard or shielding a person from exposure, there is no circumstances that any vaccine could ever be considered "necessary" to meet the exception.

discharges them for exercising any right under the OSH Act by asserting a claim in federal court without the need to first seek administrative. The 1st Cir. in *Reich v. Cambridgeport Air Systems, Inc.* 26 F. 3d 1187 (1st Cir. 1994) also recognized that the right of action does not require exhaustion of administrative remedies and that punitive damages are permissible under the OSH Act. This right of action is contained in Section 11(c)(2), as follows:

> Any employee **who believes that he has been discharged** or otherwise discriminated against by any person in violation of this subsection **may**, .. file a complaint with the Secretary alleging such discrimination. (Emphasis added)

The court's role in interpreting statutory clauses is "not to look at the statutory language in isolation, rather, the court considers the language in context…. see *Commack Self-Serv. Kosher Meats*, 680 F.3d 194, 213 (2nd Cir. 2012) Also, the cases relied on by the district court are distinguishable because they did not include the enforcement of ancillary fundamental rights under the Constitution.

The single word "may" clearly establish that Congress did not intend for employees to first exhaust any administrative review process to make a claim for wrongful discharge in Federal Court. If Congress intended otherwise, they could have used "shall" to preclude any action. Furthermore, the phrases "no person" in the beginning of Section 11(c)(1) and "any person" in Section 11(c)(2), also

establishes Congress intent to permit claims against "persons," including officials of municipalities.

The right of action in subsection (c) is listed under Section 11 titled "Judicial Review" but is separate from the enforcement powers granted to the OSHA Secretary in Sections 9 and 10 of the OSH Act. The OSHA Secretary cannot promulgate regulations or rules to limit this express private right action absent a Congressional amendment or repeal. Section 11(c) is not a standard subject to the OSHA Secretaries discretion. Section 11(c) is a statutory provision that protects the fundamental rights of employees as the *Boerne* court held Congress had power to do.

Finally, the Equal Employment Opportunity Commission (EEOC) Title VII rules and regulations regarding religious exemptions do not apply to OSHA wrongful discharge claims. While the EEOC is also an agency of the U.S. Department of Labor as is OSHA, neither the EEOC Secretary nor the OSHA Secretary have authority to limit theses rights, including the application of federal general statutes of limitations.

The gross and reckless disregard of the fundamental rights of employees by the City and other employers by applying the EEOC "reasonable accommodation" and "undue burden" standard to vaccine exemption requests gave tyrannical

discretionary power to employers to serve as the "Religious Police" evaluating religious tenants and denying fundamental rights they did not agree with or believed to be "unreasonable" or a "fraud." One Seventh-Day Adventist City employee who practices Biblical Plant-Based Lifestyle Medicine provided evidence that her dietary religious medical practice reduced contracting and experiencing serious Covid-19 by approx. 75% based on three scientific studies and her request was denied depriving her the right to practice her religious medical practice that the journals established is more effectiveness than the vaccine. (See Exhibit 26) This type of "Beast Power"[24] control the Supreme Court ruled 75 years ago was impermissible even for the courts to examine the truth or falsity of religious beliefs. See *United States v. Ballard*, 322 U.S. 78 (1944) Moreover, employers are not doctors and are incapable of evaluating medical exemptions. OSH Act provides automatic exemptions upon request without explanation.

VI. STRICT SCRUTINY APPLIES TO PLAINTIFFS SECTION 1983 CLAIMS

Section 1983 creates a cause of action against municipal entities whose officials' actions or policies, under color of state law, deprives another of "any

[24] The Pew Research Center "Religious Landscape Study of 2014" on Frequency of Reading Scripture indicates that approx. 53% of the adult U.S. population read scripture https://www.pewresearch.org/religion/religious-landscape-study/frequency-of-reading-scripture/ and by 2016 Pew reported that religious Americans believe that technologies like the Covid-19 vaccine are connected to the "mark of the beast" referenced in the book of Revelation of the Bible https://www.pewresearch.org/fact-tank/2016/07/29/the-religious-divide-on-views-of-technologies-that-would-enhance-human-beings/ -which Rev. 13:16-17 says "And he causeth all, both small and great, rich and poor, free and bond, to receive a mark in their right hand, or in their foreheads: And that no man might buy or sell, save he that had the mark, or the name of the beast, or the number of his name." Many religious City workers denied the ability to work, to receive unemployment and unable to get jobs outside the city can view the Vaccines Orders from this Biblical perspective.

rights, privileges, or immunities secured by the Constitution and laws" of the United States, 42 U.S.C. Sec. 1983, including the First Amendment right to the free exercise of religion, see, e.g., *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 320, 332 (2012). It has been established that the Vaccine Orders are unconstitutionally void and continue to cause constitutional deprivation of fundamental right. Plantiffs have met their burden of proof and are entitled to declaratory and injunctive relief. While the City's Mayor has announced a possible repeal of the Vaccine Mandates, the repeal does not preclude future mandates absent a declaration of rights by this Court. It was just two years ago that the City issued the measles mandate. Now, the City requires all employees on ILWOP to re-apply for their jobs and waive their right to backpay when the City has no right to muck such demands. The City's continual egregious actions must be stopped!!!!.

VII. THE SMITH RATIONAL BASIS TEST DOES NOT APPLY TO THE FUNDAMENTAL RIGHT TO REFUSE VACCINES

Because the Supreme Court in *Cruzan at 262* held that the right to refuse medical treatment is a fundamental right outside the Free Exercise context under

the Due Process Clause,[25] [26] and the right to refuse vaccines is no longer criminalized, the rational basis test for "neutral and generally applicable" in *Smith* cannot apply. Any deprivation of those rights must meet strict scrutiny, which no vaccine can ever do.

VIII. CONCLUSION

Declaratory and injunctive relief consistent with the proposed orders is required.

February 10, 2023

Respectfully submitted:

By: _/s/Jo Saint-George_____

Jo Saint-George, Esq,
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Attorney for Women of Color for Equal Justice, Plaintiffs and similarly situated

[25] *Washington v. Glucksberg*, 521 U.S. 702, 744 (1997) (Finding that "Cruzan rested not simply on the common-law right to refuse medical treatment, but—at least implicitly—on the even more fundamental right to make this 'deeply personal decision,'" Citing Cruzan at 289 (O'CONNOR, J., concurring)

[26] See also - *Washington v. Harper*, 494 U.S. 210, 221-22, 229 (1990) (recognizing that prisoners possess "a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment."

Updated - WC4EJ -UnFavorable TESTIMONY RE SB372.pd
Uploaded by: Jo Saint-George, Esq.
Position: UNF

SENATE BILL 372
Health Occupations – Pharmacists – Administration of Vaccines

UNFAVORABLE

Dear Chair, Vice Chair and Committee:

I am founder of the Women of Color For Equal Justice a non-profit advocacy and policy group of women lawyers who litigate and develop legislation to seek equity and equality for communities of color and women of color.

Thank you to the members of the committee for allowing me to testify today. We are opposed to the concept of SB372 and particularly the language that says that a "caregiver" can bring a child to receive a vaccination. This language must be changed to "parent/ legal representative". The bill sponsors office said that a babysitter could be considered a guardian in this situation. Children as young as 12 are allowed to babysit in the state of Maryland. Is a 12-year-old considering a caregiver?

Furthermore, the proposed bill conflicts with and is pre-empted by Federal Law 42 U.S. Code § 300aa–26 - Vaccine Information which requires:

> "each health care provider who administers a vaccine set forth in the Vaccine Injury Table **shall provide to the legal representatives of any child…"** a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials **shall be provided prior to the administration of such vaccine**.

Legal representatives include parents and legal guardians and not "babysitters". If a babysitter/caregiver is allowed to submit a 3 year-old to a pharmacist injected vaccine, then the pharmacist would violate the Federal Law which requires health care administrators to provide the federally required information to the parent or legal representative of a child "before" the vaccine is administers. Furthermore, the above Federal vaccine information standard must be complied with and is extremely important because: 1) a parent could have a religious exemption on file for the child and "babysitter" would not know that fact, 2) during a divorce – one parent who may want a child vaccinated while the other parent does not could give the child to a "caregiver/baby sitter" and have that third-party complete the vaccination over the objection of the non-consent parent, creating a big mess for family courts that are already overwhelmed with the volume of cases and 3) a babysitter will not have the detailed medical history of the child to determine if vaccination may have been counter indicated by the child's pediatrician – which would be a huge disaster if the child is injured. The caregiver would not be responsible for the lifelong care of that child. It would be the parent left with managing an injured baby possibly for the rest of the child's life and not the "caregiver".

In addition, vaccines do not "prevent" the spread of communicable diseases based on OSHA standards. See attached Emergency Motion to the 2nd Cir. Re: OSHA prohibits the use of vaccines to "prevent" the spread of airborne communicable disease.

Finally, we are deeply concerned about disenfranchised, children of color in our state who will be targeted by pharmacists who will be given a quota by their companies to give a certain amount of vaccines per day. Our concern is that poor black mothers will be offered a coupon or money to give their child a vaccine for which they may not have first determined if the vaccine is in fact counter indicated. Children of color already suffer disproportionately from chronic childhood diseases and food insecurity is truly the foundational reason for poor health outcomes for these children.

We call upon legislators to focus on providing nutrient dense whole plant-based foods to children of color to improve their over all health, reduce childhood chronic disease and communicable disease and stop relying only "pills" and "shots" to make up for what is really a problem of inadequate nutrition in children who live in food deserts and are fed animal foods that contribute to communicable and chronic disease. Do the right thing and not the cheap, expedient and irrational thing – vote no on 372.

Sincerely,

Jo Saint-George

Jo Saint-George, Esq.
Chief Legal Officer
jo@woc4equaljustice.org

See The History of Pandemics by Dr. Michael Greger, MD FACLM former Public Health Director at the HSUS in Washington DC - https://www.youtube.com/watch?v=7_ppXSABYLY&t=1705s

See Nutrition Facts - https://nutritionfacts.org/subscribe/

See Studies re: Plant-Based Diets reduction of Covid-19

See Plant-based Research Database - https://plantbasedresearch.org/

See CDC Report - Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers, Updated Oct. 14, 2021 - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinicalcare/underlyingconditions.html

See Nutritional status of micronutrients as a possible and modifiable risk factor for COVID-19: a UK perspective - British Journal of Nutrition (2021), 125, 678–684 - https://www.cambridge.org/core/services/aop-cambridgecore/content/view/35B4C4BC5B0FBD132370128EC03FE309/S000711452000330Xa.pdf/div-class-title-nutritionalstatus-of-micronutrients-as-a-possible-and-modifiable-risk-factor-for-covid-19-a-uk-perspective-div.pdf

See Plant-based diets, pescatarian diets and COVID-19 severity: a population-based case–control study in six countries – BMJ Journal Jun 2021 - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8219480/
See Diet may affect risk and severity of COVID-19 - September 8, 2021, https://www.sciencedaily.com/releases/2021/09/210908180530.htm

SenateBill372(PDFwrd).pdf
Uploaded by: John Kelly
Position: UNF

Oppose Senate Bill 372

Before the Senate Finance Committee

of the

Maryland General Assembly

Hearing on SB 372

February 28, 2023

Written Testimony in Opposition to Senate Bill 372

John M. Kelly

Bethesda, Maryland

Senate Bill 373 is an assault on the children's health masked as an effort to protect them. If, as assumed, children have the capacity to make decisions about the risks and benefits of taking a vaccine, then, by the same logic, they should be allowed to make decisions about possessing loaded firearms so they can better protect themselves against the danger of assault.

Obvious reasons for opposing the bill are that it: (1) violates fundamental parental rights; (2) ignores informed consent; (3) falsely assumes there is a public health emergency; (4) neglects the medical history of minors; (5) assumes that pharmacists with only 20 hours of additional education are qualified to respond to serious adverse vaccine reactions; (6) ignores evidence to the contrary that vaccines listed on the CDC's (Center for Disease Control and Prevention) recommended schedule have been properly tested and are safe and effective; (7) ignores evidence to the contrary that vaccines approved and authorized by the US. Food and Drug Administration are safe and effective; (8) and assumes minors have the capacity, legal or otherwise, to make informed choices about whether to take a vaccine.

These and other shortcomings in the bill rest on two fundamental flaws: the violation of fundamental parental rights and the and the grossly mistaken assumption that minor children have the capacity to make informed decisions about vaccines. This testimony focuses on them.

In regard to parental rights, the central issue is: Who will makes decisions for minor children, the government or parents? In the history of the United States and other countries the primary authority and responsibly of parents to raise their children has been taken for granted so long as a parent adequately cares for his or her children. Several US Supreme Court rulings have affirmed the primary right of parents in raising their children.

Consequently, it is necessary to ask: What authority the bill relies to allow the state government to usurp fundamental parental rights regarding vaccination of their minor children? The only authority suggested in the bill is that there is a “state of emergency”. But it does not say what the emergency is. It can not identify one because there is no emergency. On this basis alone the bill should be rejected. Even if there where an emergency that fact alone is not sufficient grounds to abrogate parental rights in such a sweeping manner.

The bill ignores over two hundred thirty years of US. history and a hundred years of US Supreme Court precedents recognizing parental rights as traditional rights. Not until a hundred years ago in 1923 were traditional parental rights challenged, and the Court ruled (in Myer v. Neb.) that parental rights are a fundamental right and ruled in favor of the parents. Two years later the Court affirmed these rights (in Pierce v. Society of Sisters) saying that parents are not the mere creatures of the state and that liberty provides that parents are the ones to make decisions about raising their children. In 1972 the Court (in Wisconsin v. Yoder) affirmed parental rights stating:

> “The history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. This primary role of the parents in the upbringing of their children is now established beyond debate as an enduring American tradition”.

In 2000 the Court (in the Troxel v. Granville) in upholding parental rights cited an earlier court opinion which stated:

> “[O]ur constitutional system long ago rejected any notion that a child is the mere creature of the State and, on the contrary, asserted that parents generally have the right, coupled with the high duty, to recognize and prepare [their children] for additional obligations. The law’s concept of the family rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life’s difficult decisions. More important, historically it has recognized that natural bonds of affection lead parents to act in the best interests of their children.”

In the cited opinion the only qualification was if a parent were not adequately caring for his or her children. Absent that “... there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent’s children.”

Most recently, this past fall the federal district court for Washington, DC. blocked the

implementation of a law that would allow children to receive vaccinations without the knowledge or approval of their parents. These court decisions affirm that "parental rights" are a "fundamental rights", the highest right in our legal system and should never be ignored. Senate Bill 372 blatantly ignores them.

Further, the bill's assumption that minor children have the capacity, legal or otherwise, to make informed decisions about receiving a vaccine is clearly unreasonable. Children do not have the knowledge, experience and judgment to make decisions about the necessity of vaccines or to weigh their respective risks and benefits. This is precisely the issue the Court addressed in Troxel v. Granville when it stated: "...Parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions".

It is important to note that while the assertion the Court makes in Wisconsin v. Yoder that the "primary role of the parents in the upbringing of their children is now established beyond debate", the same certainty does not apply to the safety and effectiveness of vaccines. The latter fact is evidenced by contentious debates among leading scientists and doctors, and more importantly and painfully by tens of thousands of children with recognized injuries and death from vaccines.* Consequently, the judgment of parents is required to make decisions about vaccines for their minor children.

Voluntary consent is not sufficient even for an adult receiving a vaccine let alone a child. A person must have the legal capacity to give consent. And to be able to give *informed consent*, the person must be provided with information about the risks and benefits of, and the alternatives to a proposed medical treatment.

It is grossly unreasonable to expect a child to ask and understand answers to basic questions such as:

1. If the vaccine was tested in a pre-licensure clinical trial with a *real* placebo;
[As of 2017 none of the mandated childhood vaccines had been tested for safety in pre-licensure tests with *real* placebos.]
2. If the vaccine was not tested against a real placebo, how can the true rate of adverse effects be calculated?
3. Is there a medical test that can be performed to determine if there is a high risk of being injured by the vaccine?
4. What types of, and how many serious injuries have been reported from the vaccine, and where is it available?

5. Where is information on relative risks and benefits of the vaccine?

6. Is there evidence that children who take the vaccine have significantly worse outcomes than those who do not?; and

7. What do the technical terms in the information sheet included with the vaccine mean?

The difficulty for children obtaining the necessary information to properly give informed consent became even more challenging the past two years with the roll-out of the COVID-19 vaccine. Scientific debate was censored and alternative health care interventions were suppressed. It was and continues to be difficult even for adults to find out basic information about the vaccine and alternatives in order to make informed decisions. To expect children to do is unrealistic.

For example, children do not have the capacity to ask probing questions or evaluate the meaning and significance of information and issues such as:

1. Whether the COVID-19 mRNA vaccine stays near the point of injection or enters the bloodstream and accumulates in several organs;

2. Understand the FDA's June 2021 revision of its Fact Sheets for Pfizer-BioNTech and Moderna COVID-19 vaccines that added a warning about the increased risks of inflammation of the heart muscle and inflammation of the tissue surrounding the heart (myocarditis and pericarditis, respectively);

3. Understand the CDC and FDA's "Vaccine Adverse Events Reporting System" which is intended to be an early warning system to detect possible safety problems with vaccines. (More than 32 thousand deaths and more than 260 thousand serious injuries including deaths have been reported for COVID-19 vaccines. These deaths and injuries are more than have been reported for all other vaccines since 1990. In addition, it is widely recognized that the vaccine injuries are greatly under-reported);

4. Why the ingredients of the COVID-19 vaccine injected into people are not fully disclosed?; and

5. Why one of the vaccine manufactures wants seventy years to release data about the clinical trials of its COVID vaccine?

There are many other issues and questions such as these that are important, complex and contentious. It takes great effort and time for most adults to understand the complex facts and issues involving vaccines and weigh the pros and cons. Children are in no position to do so, and it is nothing short of preposterous to suppose they do.

For all the above reasons, both individually and collectively, Senate Bill 372 should be opposed.

*See these sources for the contentious debate over vaccines: ***The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health***, Robert F. Kennedy Jr. (2021); ***Lies My Government Told Me: And the Better Future Coming***, Robert W. Malone (2022); ***Turtles All the Way Down: Vaccine Science and Myth***, Edited by Zoey O'Toole and Mary Holland (2022); ***The Courage to Face COVID-19: Preventing Hospitalization and Death While Battling the Bio-Pharmaceutical Complex***, John Leake and Peter McCullough (2022); ***The Truth about COVID-19: Exposing the Great Reset, Lockdowns, Vaccine Passports and the New Normal***, Dr. Joseph Mercola and Ronnie Cummins; ***The New Abnormal: The Rise of the Biomedical Security State***, Aaron Kheriaty (2022); ***COVID-19 and the Global Predators: We are the Prey***, Peter R. Breggin and Ginger Ross Breggin (2021); ***Cause Unknown: The Epidemic of Sudden Deaths in 2021 and 2022***, Edward Dowd (2022)

SB0372 oppose.pdf
Uploaded by: Julie Sharpe
Position: UNF

SB0372 oppose

Dear Chairman Augustine and Members of the Finance Committee,

I am a mom of four school-aged kids and wife of a person suffering with lifelong epilepsy. My mom also lives with us because of her own health struggles.

My husband had brain surgery one year ago to control his seizures, but he still requires anti seizure medications. I count on the pharmacist to be alert and present when they fill my husband's prescriptions. Filling the prescription accurately means my husband can function in his daily life. Seizures knock him out for at at lease half a day. Seizures mean he can't drive for months. Maintaining proper levels of the meds in his blood means he lives a better life. Mistakes in filling his prescriptions can be serious.

Over the past twenty years, many times the neurologist has changed my husband's meds. Every time, insurance and pharmacies and doctors have had to coordinate communication. There have been countless times I've been alerted a prescription is ready, and I've gone to pick it up only to find that actually the preapproval still needed to be submitted or it was the wrong dosage or they accidentally refilled instead of changed the med, or they substituted with a generic when in this case, the name brand drug was essential because of precision standards, or there was some other problem.

Pharmacists are busy; these issues are just a little of what is keeping them busy. The prescriptions they fill are a tiny part of their busy days, and they are fallible human beings. They are making mistakes without any added responsibilities.

It is dangerous to ask a pharmacist to be busy with their regular job and then add on something as important as childhood vaccines. In my experience, pharmacists have demonstrated the challenge of successfully multitasking their existing responsibilities: consulting with patients, communicating with stakeholders, filling prescriptions and their other things. Vaccinating kids is a very different type of work. The extra burden will lead to more mistakes and will endanger patients.

I oppose SB0372 which would allow pharmacists to vaccinate children. Thank you for voting NO.

Sincerely,

Julie Sharpe
3980 Hunting Creek Rd
Huntingtown MD 20639

UNFAV_SB0372.pdf
Uploaded by: Kara Fisher
Position: UNF

SB0372: Health Occupations - Pharmacists - Administration of Vaccines

UNFAVORABLE

Kara Fisher

Dear Madam Chair, Madam Vice Chair and Senate Finance Committee:

I ask you to oppose SB 372 that would allow pharmacists to administer vaccines to elementary age children.

The primary care physician's office is the optimal care setting for delivery of any medical treatment.

The bill should include language to require a **parent or legal guardian** to be present for any immunization.

My cousin's child went into anaphylactic shock after receiving the Covid vaccine in a Walgreens. Her mother was happy to be there when her daughter hit the floor. A **caregiver** or babysitter, who accompanies the child, is not always equipped to handle an emergency situation or advocate for the child's medical needs.

Thank you.

Kara Fisher

Rockville, District 19

Please oppose SB372.pdf
Uploaded by: Karen McCullough
Position: UNF

2/27/2023

RE: Please oppose SB372

Hello, please oppose SB372.

How on earth is a pharmacy technician qualified after 6 weeks of training to know the contraindications of administering vaccines to my child without knowing their health history. Pediatricians are trained to properly access risk factors and pharmacist are not. It is absolutely unbelievable that government officials feel they should be making laws like this that they hold no one liable when something goes wrong, and EVERYTHING falls on the parent. The pharmaceutical company isn't held liable do the 1986 National Childhood Vaccine Injury Act, the doctors, pharmacist, government will all have immunity when something goes wrong and a child is serious harmed and/or dies.

I am a Maryland citizen and will be watching this bill closely and voting accordingly in the next

Regard Karen

2023SB372pharmacy2.pdf
Uploaded by: Kathy Talbott
Position: UNF

UNFAVORABLE SB372

Kathy Talbott, Myersville, MD

To the Honorable Finance Committee Members,

Please say NO to SB372. This bill is unnecessary, and potentially dangerous. I am opposed. An unfavorable report is needed.

Thank you for your time and dedicated efforts on behalf of Maryland's families.

Kathy Talbott

sb0372F.pdf
Uploaded by: kim chambers
Position: UNF

SENATE BILL 372

J2 EMERGENCY BILL 3lr1626
CF 3lr3001

By: **Senator Augustine**
Introduced and read first time: February 1, 2023
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Health Occupations – Pharmacists – Administration of Vaccines

FOR the purpose of authorizing a pharmacist to order and administer certain vaccinations to an individual in a certain age group if certain requirements are met; altering the age of an individual to whom a pharmacist may administer certain vaccinations; repealing the requirement that a pharmacist administer certain vaccinations under a written protocol; authorizing a pharmacist to administer certain vaccinations to an adult; and generally relating to the administration of vaccinations by pharmacists.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–508
Annotated Code of Maryland
(2021 Replacement Volume and 2022 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health Occupations

12–508.

(a) (1) **[**Subject to subsection (c) of this section, a pharmacist may administer an influenza vaccination to an individual who is at least 9 years old, in accordance with regulations adopted by the Board, in consultation with the Department.

(2) Subject to subsection (c) of this section, a**]** **A** pharmacist may **ORDER AND** administer a vaccination **[**that**]** **TO AN INDIVIDUAL WHO IS AT LEAST 3 YEARS OLD BUT UNDER THE AGE OF 18 YEARS IF:**

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

(I) 1. THE VACCINE is listed in the Centers for Disease Control and Prevention's Recommended Immunization Schedule **[**to an individual who:

(i) Is at least 11 years old but under the age of 18 years; and

(ii) Has a prescription from an authorized prescriber**]; OR**

2. THE VACCINE IS APPROVED OR AUTHORIZED BY THE U.S. FOOD AND DRUG ADMINISTRATION;

(II) THE PHARMACIST HAS COMPLETED A PRACTICAL TRAINING PROGRAM OF AT LEAST 20 HOURS THAT IS APPROVED BY THE ACCREDITATION COUNCIL FOR PHARMACY EDUCATION AND INCLUDES:

1. HANDS–ON INJECTION TECHNIQUES;

2. CLINICAL EVALUATION OF INDICATIONS AND CONTRAINDICATIONS OF VACCINES; AND

3. THE RECOGNITION AND TREATMENT OF EMERGENCY REACTIONS TO VACCINES;

(III) THE PHARMACIST HAS A CURRENT CERTIFICATE IN BASIC CARDIOPULMONARY RESUSCITATION;

(IV) THE PHARMACIST HAS COMPLETED A MINIMUM OF 2 HOURS OF CONTINUING PHARMACEUTICAL EDUCATION RELATED TO IMMUNIZATIONS THAT IS APPROVED BY THE ACCREDITATION COUNCIL FOR PHARMACY EDUCATION AS PART OF THE LICENSE RENEWAL REQUIREMENTS UNDER § 12–309 OF THIS TITLE;

(V) THE PHARMACIST COMPLIES WITH THE RECORD–KEEPING AND REPORTING REQUIREMENTS IN PARAGRAPH (3) OF THIS SUBSECTION AND ANY CORRESPONDING REGULATIONS ADOPTED BY THE BOARD; AND

(VI) THE PHARMACIST INFORMS EACH CHILD VACCINATION PATIENT AND ADULT CAREGIVER WHO IS ACCOMPANYING THE CHILD OF THE IMPORTANCE OF WELL–CHILD VISITS WITH A PEDIATRIC PRIMARY CARE PROVIDER AND REFERS THE PATIENT TO A PEDIATRIC PRIMARY CARE PROVIDER WHEN APPROPRIATE.

[(3)**] (2) [**(i) Subject to subparagraph (ii) of this paragraph, a**] A** pharmacist may administer to an adult a vaccination that is:

[1.**] (I)** Listed in the Centers for Disease Control and Prevention's Recommended Immunization Schedule; **[**or**]**

[2.**] (II)** Recommended in the Centers for Disease Control and Prevention's Health Information for International Travel**; OR**

(III) APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION.

[(ii) A pharmacist shall administer a vaccination under subparagraph (i) of this paragraph under a written protocol that:

1. Is vaccine specific; and

2. Meets criteria established by the Department, in consultation with the Board, the Board of Physicians, and the Board of Nursing, in regulation.**]**

[(4)**] (3)** A pharmacist shall:

(i) Report all vaccinations administered by the pharmacist to the ImmuNet Program established under § 18–109 of the Health – General Article;

(ii) If the vaccination has been administered in accordance with a prescription, document at least one effort to inform the individual's authorized prescriber that the vaccination has been administered; and

(iii) **[**For a vaccination administered under paragraph (2) or (3)**]** **EXCEPT FOR AN INFLUENZA VACCINATION ADMINISTERED UNDER PARAGRAPH (1)** of this subsection, if the authorized prescriber is not the individual's primary care provider or if the vaccination has not been administered in accordance with a prescription, document at least one effort to inform the individual's primary care provider or other usual source of care that the vaccination has been administered.

(b) The Board shall:

(1) Set reasonable fees for the administration of vaccinations under this section; and

(2) Adopt regulations that require a pharmacist to submit a registration form to the Board that includes verification that the pharmacist:

(i) Has successfully completed a certification course approved by the Board that included instruction in the guidelines and recommendations of the Centers for Disease Control and Prevention regarding vaccinations; and

(ii) Is certified in basic cardiopulmonary resuscitation and obtained the certification through in–person classroom instruction.

[(c) From July 1, 2021, to June 30, 2023, inclusive, a pharmacist may administer a vaccine to an individual who is at least 3 years old but under the age of 18 years if:

(1) The vaccine is approved by the U.S. Food and Drug Administration;

(2) The vaccination is ordered and administered in accordance with the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices immunization schedules;

(3) The pharmacist has completed a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education and includes:

(i) Hands–on injection techniques;

(ii) Clinical evaluation of indications and contraindications of vaccines; and

(iii) The recognition and treatment of emergency reactions to vaccines;

(4) The pharmacist has a current certificate in basic cardiopulmonary resuscitation;

(5) The pharmacist has completed a minimum of 2 hours of continuing pharmaceutical education related to immunizations that is approved by the Accreditation Council for Pharmacy Education as part of the license renewal requirements under § 12–309 of this title;

(6) The pharmacist complies with the record–keeping and reporting requirements in subsection (a)(4) of this section and the corresponding regulations; and

(7) The pharmacist informs each child vaccination patient and adult caregiver who is accompanying the child of the importance of well–child visits with a pediatric primary care provider and refers the patient to a pediatric primary care provider when appropriate.**]**

SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has been passed by a yea and nay vote supported by three–fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is enacted.

testimonyagainstSB372.pdf
Uploaded by: KRISHNA MANOHAR
Position: UNF

Hello everyone,

My name is Krishna Manohar and I am a resident of district 17 and I strongly oppose SB 372. This bill takes away the parental rights over children's health. The pandemic emergency is over as declared by President Biden and this bill is being rushed in as if there is still a crisis going on. Despite their training, pharmacists are not as knowledgeable and capable to handle any adverse effects the patient might experience as a skilled licensed pediatrician would. The pharmacist will not be held responsible for any injuries brought on by the vaccination of the child and the parent will not be able to get the answers as to what happened to their child. This bill seems motivated by greed with no regard for the consequences that will befall the uninformed and compliant public. As an uncle of two young boys I urging you to vote against this bill. Thank you and good day.

OPPOSE SB372- Health Occupations - Pharmacists - A
Uploaded by: Linda Diefenbach
Position: UNF

Members of the Finance Committee
OPPOSE-SB372-Health Occupations - Pharmacists - Administration of Vaccines.

Dear Senators,
I oppose SB 372 and respectfully request that you vote against it.

My objections to this bill are numerous. Once again there is the issue of minors being vaccinated without parents knowledge or consent. This is problematic and should never be done.

A pharmacy or grocery is not the appropriate place for pediatric immunizations. Pharmacists are not doctors, do not know the child's medical history and do not have a medical relationship with that child or the family.

It is only after a child's pediatrician performs a thorough assessment of a child should a child receive a vaccination.

Expanding pharmacist administration of vaccines is not in the best interest of children, and it is not optimal for safety or for successful outcomes. Children are not vaccinated like adults and have a very complicated recommended schedule, sometimes receiving multiple vaccines at once.

I'm asking the Finance Committee to OPPOSE SB 372.

Sincerely,
Linda Diefenbach
Middletown, MD

Unfavorable SB 372.pdf
Uploaded by: Lori Vaughn
Position: UNF

OPPOSE SB 0372

From: Lori Vaughn (lovaughn21@yahoo.com)

To: melony.griffith@senate.state.md.us; pamela.beidle@senate.state.md.us; arthur.ellis@senate.state.md.us; dawn.gile@senate.state.md.us; antonio.hayes@senate.state.md.us; steve.hershey@senate.state.md.us; ben.kramer@senate.state.md.us; johnny.mautz@senate.state.md.us; justin.ready@senate.state.md.us; katherine.klausmeier@senate.state.md.us; clarence.lam@senate.state.md.us

Date: Monday, February 27, 2023 at 11:46 AM EST

Good morning Senators,

OPPOSE SB 0372!!!! As a resident of South Laurel and a mother of five, I'm emailing to convey my concern for proposed Senate Bill 0372 and respectfully request you OPPOSE this bill.

SB 372 gives pharmacists authority over parents to administer vaccines, without their knowledge or consent. This is wrong as no individual nor entity (medical professional or otherwise) supersedes a parent's authority. This bill was filed as an emergency yet there is currently NO emergency, as former Governor Hogan lifted such emergency in February 2022. Further, pharmacists are not doctors nor do they have an intimate relationship with a child regarding their health and medical history. Additionally, pharmacists are not equipped to deal with adverse events that may occur nor are they liable if such an injury happens. Finally, it is unclear who is billed for these procedures.

Our children are our future. Please don't jeopardize our children by this irresponsible proposed bill. OPPOSE SB 0372!!

Respectfully,
Lori Vaughn

Opposed to SB 372 2-27-23.pdf
Uploaded by: Marco Colombini
Position: UNF

Opposed to SB 372

No vaccination of children without informing parents of the real risks of the vaccine. mRNA vaccines have caused children to become paralyzed and even die.

Marco Colombini

17520 Doctor Bird Road, Sandy Spring, MD

SB0372 Testimony - Stoklosa.pdf
Uploaded by: Margaret Stoklosa
Position: UNF

Dear Committee Members,

As a parent, I urge you to please **OPPOSE** SB0372.

Administration of vaccines should be completed under a strict parent/ physician relationship. These substances require a full medical evaluation and pharmacists are not trained to provide this service, as they are trained to dispense drugs and not make determinations on whether a drug can be administered in a given moment. There is no need to expand their scope for the following reasons:

1. Pharmacists are making mistakes with medications. **Improper dispensing of medications results in medication error rates up to 55% (*BMJ Open Quality*, 2018).** Perhaps we should be focusing on how to avoid these errors versus expanding their scope?
   https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html
   https://www.singlecare.com/blog/news/medication-errors-statistics/

2. Vaccines are medical products with guidelines and contraindications. The pediatric immunization schedule is complicated, and pharmacists are not trained to understand the nuances to immune system stimulation, especially in a chaotic, non-secure pharmacy environment. How would follow-up be completed? How would potential adverse reactions be documented and addressed? Pharmacists have no time to think about the downstream effects in their rushed environments.

3. More and more pharmacies are also marketing vaccines as lead magnets - providing incentives to consumers to come in and have one. They are treating vaccines as cash cows for their "business" (https://www.pbahealth.com/how-to-make-immunizations-a-pharmacy-profit-center/?fbclid=IwAR2h1fCobBWU8jpQpnjvgx-lF689FxiGmApv9hWrEpgYjd3dOv0t5eA9gdY). Call me conservative, but the health of myself and my children is not a business and never should be.

This bill opens the possibility of increased harm to children. Please OPPOSE SB0372.

Thank you,
Margaret Stoklosa
803 Main St.
Gaithersburg, MD 20878

Oppose SB372.pdf
Uploaded by: Mark Meyerovich
Position: UNF

Oppose SB 372

- 20 hours is not sufficient time to train for or gain experience to administer vaccines, especially to small children. It is well known that many injuries associated with receipt of vaccines are due to improper administration.

- Administration of vaccines to children without reviewing the child's medical chart, assessing contraindications, or evaluating the condition of the patient following the administration of the vaccine significantly increases the risk. Adverse reactions may be undetected and unreported to their primary care provider.

- The CDC Director clearly stated in the Congress that the only reason Covid vaccine was added to the childhood schedule was so it would be included in the Vaccines for Children program. There is compelling evidence that Covid vaccines confer more risk than benefit to patients aged 3-18. Pharmacists cannot accurately assess the risk versus benefit to pediatric patients. Decisions to give vaccines to children should be left with pediatricians working with the child's parents.

- There is no evidence that expanding the scope of providers licensed to administer vaccines to small children improves health outcomes for those children, while conversely there is apparent risk to children in doing so. There is strong evidence that the bill will do harm, thus it must be rejected.

Sincerely,
Mark Meyerovich
Gaithersburg, MD

SB 372 LOO unless amended 2023 Leg NAPNAP.pdf
Uploaded by: MD Chesapake NAPNAP
Position: UNF

National Association of Pediatric Nurse Practitioners℠
MD: CHESAPEAKE

Oppose unless amended: SB 372 Health Occupations - Pharmacists - Administration of Vaccines

2/24/2023

Maryland Senate
Finance Committee
3 East
Miller Office Senate Building
Annapolis, Maryland 21401

Dear Honorable Chair, Vice-Chair and Members of the Committee:

On behalf of the pediatric nurse practitioners (PNPs) and fellow pediatric-focused advanced practice registered nurses (APRNs) of the National Association of Pediatric Nurse Practitioners (NAPNAP) Chesapeake Chapter, I am writing to express our opposition of **SB 372 Health Occupations-Pharmacists - Administration of Vaccines unless amended.**

This legislation would allow pharmacists to be able to administer vaccines approved and licensed by the FDA and administered according to the schedule established by the CDC's Advisory Committee on Immunization Practices to children as young as 3 years old. We know that pharmacies have consistently increased annual influenza vaccination rates and most recently significantly supported the uptake of COVID-19 vaccines. We are grateful that the bill includes language that discusses the importance of well visits with patients and adult caregivers.

We understand the need for vaccinations to be available across many health care locations to increase access to care and vaccination rates. However we are concerned with the minimum age requirement and the required reporting documentation to IMMUNET. We suggest amending the age to 5 years, allowance for influenza and emergency vaccination only, and requiring all vaccinations including influenza vaccination be entered into IMMUNET.

We do not want to miss opportunities to see patients for vaccinations at their annual child visits under 5 years of age as significant developmental surveillance is completed. In addition to immunizations, providers routinely perform preventive screening, routine exam updates, counseling and anticipatory guidance. We also address vaccination questions and hesitancy. By shifting routine

Sincerely,

Lindsay J. Ward CRNP, RN, IBCLC, MSN, BSN
Certified Registered Nurse Practitioner- Pediatric Primary Care
International Board-Certified Lactation Consultant
National Association of Pediatric Nurse Practitioners (NAPNAP)
Chesapeake Chapter President

National Association of Pediatric Nurse Practitioners℠
MD: CHESAPEAKE

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Evgenia Ogordova

Evgenia Ogordova-DNP
National Association of Pediatric Nurse Practitioners (NAPNAP)
Chesapeake Chapter Legislative Chair

SB372 UNFAVORABLE Love Maryland PAC.pdf
Uploaded by: MEGAN MONTGOMERY
Position: UNF

SB372: Health Occupations- Pharmacists- Administration of Vaccines
UNFAVORABLE
Love Maryland PAC

Dear Chair Griffith, Vice Chair Klausmeier, and Distinguished Members of the Finance Committee,

The Love Maryland PAC asks for an UNFAVORABLE report on SB372 for the following reasons:

1. Best Health Outcomes- The best health outcomes for children occur when the parent and the physician work as a team and consider health history, precautions, and contraindications before making any medical decisions. Children are not vaccinated like adults and have a very complex recommended schedule, receiving multiple shots at once. Should this bill ever pass, children will miss out important well child visits with their pediatricians. Pediatricians perform a comprehensive assessment of the whole child including screening for growth issues, heart irregularities, neurodevelopmental delays and in the adolescent years screening for signs of abuse, mental health concerns, and scoliosis. If childhood vaccines are given in a pharmacy in our state, parents will stop taking their children for pediatric visits.

2. Training- Pediatricians are specifically trained to assess children for vaccine appropriateness and readiness. Immunizations are pharmaceutical products that come with warnings, precautions, and contraindications. A child must be properly assessed prior to administration to reduce risk for serious harm and/or death. A pharmacist does not have this training and will not acquire it with 20 hours of education as the bill proposes.

3. Immunet/ Missing State Study- In 2021 the Federal PREP Act did allow pharmacists to vaccinate children as young as 3 as part of the emergency measures to deal with the Covid pandemic. The state of Maryland legislated a study of this time period to gather information. This study has not been done! A preliminary study showed a sharp decrease in reporting to Immunet from 2018-2020. A 2017 Maryland law required that all vaccine providers report that vaccine in the state's Immunet system. In 2018, about 70% of providers were reporting. By 2020, this number fell to 47%. One difference is that pharmacists started administering more vaccinations during this time. SB 372 can never be considered without the state's study.

4. **Liability-** The Federal 1986 National Childhood Vaccine Injury Act removed liability from vaccine makers as well as the provider that administers the vaccine for any shot on the Childhood Schedule. Pharmacists have not been trained in assessment for childhood vaccines and will not be liable for any mistake that they make with children. This puts children at risk.

5. Pharmacies Are Chaotic- Pharmacies have a reputation for being chaotic. Pharmacist's jobs are harder than ever as so many people are on multiple pharmaceutical products. It is dangerous to have pharmacists stop filling a prescription every time they have to give shots. A screaming toddler or preschooler should not be assessed for vaccine appropriateness in the middle of a crowded Walmart.

6. Improper Injections- SIRVA (Shoulder Injury Related to Vaccine Administration) have risen dramatically since pharmacies started giving vaccinations. A skyrocketing number of cases have been compensated by the Federal Government as people are getting their shots outside of their doctor's offices.

7. **Pediatric Care-** People who become pharmacists are smart enough to have gone to medical school, physician assistant training, and/or nursing school. Many chose the pharmacy profession because they did not have an interest in direct patient care. They certainly did not choose to go into pediatrics which requires a level of patience and an ability to make a child feel safe and comfortable that cannot be taught. Not all pharmacists want to do direct patient care with screaming children.

We ask the committee for an UNFAVORABLE report. This bill is a solution looking for a problem, as children can already receive their vaccinations in an urgent care setting where they will also getting basic vital signs and assessment by a licensed caregiver.

Please see following attachments as evidence for the above statement.

SB372-INFO-How to Make Immunizations a Pharmacy Pr
Uploaded by: MEGAN MONTGOMERY
Position: UNF

How to Make Immunizations a Pharmacy Profit Center

March 15, 2019

When Beverly Schaefer became one of the first pharmacists to administer flu shots in 1996, she could never have guessed that twenty years later she'd be administering nearly thirteen thousand immunizations per year.

Schaefer says her pharmacy was the first in the U.S. to offer mass immunizations administered by a pharmacist, and the reason she pioneered the idea came down to a business problem. She had turned down a contract from a major payer and all at once she lost 300 patients. Searching for a way to retain their business even while they were getting their prescriptions somewhere else, she ordered the flu vaccine and posted a sign on her door.

"We were hoping to do 300 flu shots the first year," she said. "We did 1,200. The biggest problem is that we had to go to the bank twice a day because we had so many tens and twenties in the till."

At that time they gave the shots out of a backroom with a table and a couple of chairs. When people came in to get the shots, they kept asking what else the pharmacy was going to offer back there. "It was like a light bulb went off," Schaefer said. "What people want is access to healthcare." Now her pharmacy, Katterman's Sand Point Pharmacy, has become a true immunization destination, offering 28 vaccines year-round. They account for nearly 20 percent of her business and 30 percent of her profit.

"If you want to add profit to your bottom line, increase the number of immunizations that you're doing," Schaefer said. "Every single immunization that you do adds to your bottom line. There are no

exceptions."

Marty Feltner, director of immunization services for Kohll's Pharmacy, also pioneered immunization in his home state of Nebraska. As the first pharmacy in the state to offer immunizations, Kohll's has become the immunization leader in the region. "It's another added component to bring in another revenue stream," Feltner said. "When you look at pharmacies today, they're pretty much breakeven pharmacies. So in order to be positive, as far as revenue stream, you've got to think outside the box." Among its eight locations, Kohll's administers 50,000 to 80,000 flu immunizations per year.

Both Katterman's and Kohll's specialize in travel immunizations, which in itself has been a boon for business. People travel from hours away to get travel shots from their pharmacies. Around half of Schaefer's total immunization revenue comes from travel vaccines.

They both believe immunizations have become essential to compete in today's world, especially as a way to differentiate from online and mail-order pharmacies that are capturing more and more of the market share. "You know that [Bezos] family that sends boxes to every house every day across the country?" Schaefer said, whose pharmacy is in Seattle, the location of Amazon's headquarters. "They have to come to my store to get travel immunizations. Because you can't do that by mail. So why not offer a service that mail order will never be able to compete with?"

A Golden Opportunity

Around 100 million Americans get the flu shot every year, which produces around $4 billion to $5 billion in revenue. That's just influenza. Each year, the national chain pharmacies and big-box stores battle to snatch up patients to their immunization programs with aggressive marketing and significant discounts.

Yet the immunization market is still largely untapped. A 2017 report from the Centers for Disease Control and Prevention stated that vaccination rates have a long way to go to meet the *Healthy People 2020* goals. And pharmacies can be the prime beneficiaries of this growing demand. Surveys show that patients find pharmacies to be more accessible and convenient than physicians' offices and health clinics. And the majority of people in the U.S. now prefer getting vaccinated at the pharmacy, according to
a survey by PrescribeWellness.

Many independent pharmacies have already caught on to this trend. The 2018 *NCPA Digest* shows 70 percent of pharmacies offering immunizations. However, that number includes pharmacies that only offer the flu shot. Another estimate says less than a quarter of independents offer immunizations beyond influenza. And the flu shot is only the tip of the immunization iceberg. There's a glacial immunization opportunity beyond influenza waiting to be uncovered. For example, flu shots bring in roughly $20 of profit a pop. Compare that to meningococcal group B vaccine at $48, human papillomavirus at $50, and hepatitis B at $80, according to one estimate. An independent pharmacy in Louisiana earned nearly $6,000 in profit from only 70 shots of hep B in the first year of offering the vaccine.

"If you want to add profit to your bottom line, increase the number of immunizations that you're doing. Every single immunization that you do adds to your bottom line. There are no exceptions."

Multiple pharmacy experts say pharmacies that offer expanded immunizations can expect a minimum $40K per year in additional revenue, but more likely closer to $90K. One independent pharmacy in Oklahoma gave 1,800 vaccines in one year, earning $40K in pure profit. Another independent pharmacy in Pennsylvania averaged more than 700 immunizations in its second year, resulting in more than $16K in profit.

"You do two or three new consultations a day, your profit on just those consultations could potentially pay for that pharmacist just to be there that day," Feltner said. "There are times where we'll get five or seven consultations in one day and have profitability of three or four hundred dollars on just that one-hour appointment depending on the patient's travel designation."

Schaefer said the least amount of profit you'll ever make on a vaccine is $15 to $20. You essentially get paid twice, once for the product and once for the service itself. "How many prescriptions do you make fifteen to twenty dollars on?"

Immunizations also provide additional business benefits to indirectly increase revenue and profitability. "What we're finding is that pharmacies and pharmacists who are engaging in immunizations are being approached for other patient care activities," said Mitch Rothholz, chief strategy officer for the American

Pharmacists Association (APhA). “Coming in for immunizations is an opportunity to talk about other healthcare services they might need that the pharmacy can provide.”

That has been true in Feltner’s experience, especially for the shingles vaccine, which is suffering shortages because demand is so high. “You’re going to have lots of patients come into the pharmacy who may not be a regular customer and by offering the service you get them in the door,” he said. “If we say we offer the shingles vaccine, we may be able to transfer their prescription business over to our pharmacy just by having an immunization program. It just opens more doors.”

A broad and lasting benefit, immunizations move your pharmacy in the direction the profession is headed: from medication-focused to patient-focused care. “It’s a demonstration of pharmacists as a healthcare provider,” Rothholz said. “Because pharmacists are trying to move and expand their services into a more quality patient care delivery activity versus just providing a product. Pharmacists’ value to patients and the healthcare team is recognized when patients receive the appropriate medication or healthcare service and achieve the optimal benefit from those services.”

The addition of patient-centered services not only sets you up to survive the future of pharmacy, it also helps nurture patient loyalty. It’s one of the few opportunities pharmacists have to meet face-to-face with patients. “You’ll have a patient for life once you start immunizing,” Feltner said. “It’s been a very rewarding experience.”

Easy as 1, 2, 3

Many pharmacies don’t offer immunizations because the thought of an immunization program is overwhelming. After all, it’s a whole new addition that requires you to spend time and money ordering and storing new inventory, marketing new services, and most importantly, fitting it into your already busy workflow.

But Feltner and Schaefer said the difficulty of offering immunizations is a major misconception that keeps too many pharmacies away. In fact, adding an immunization program is really easy, they said.

You simply treat immunizations like prescriptions. When someone asks for an immunization, your process follows just as if they handed you a prescription. You give them a consent form, enter their insurance info, ring them up, and when they get to the front of the queue, the pharmacist brings them to

the consultation room and administers the vaccine. “Doing an immunization takes about as much time as filling a new prescription,” Schaefer said. “It’s like entering a new patient.”

Vaccines are ordered from your primary wholesaler (or possibly direct from the manufacturer) and stored in your refrigerator with your insulins and other refrigerated medicine, or they’re stored in your freezer. In other words, they fit right in alongside all your other prescription medicines.

But the only way to make the integration seamless is to utilize your employees well. Every part of the process should be conducted by technicians except for reviewing the documentation and administering the vaccine, which doesn’t take more than a couple of minutes of the pharmacist’s time. If you have a pharmacist who’s a recent graduate, consider letting them take the reins. “They’ve been trained in college to do this,” Schaefer said. “Give it to the youngest one and let them be in charge of it if you trust them.”

Feltner suggests starting out slow, with the flu, shingles, and pneumonia vaccines, and working your way up from there. “You can get a vaccine program up and running very, very quickly,” he said. He and Schaefer both grew their immunization programs gradually, adding vaccines to their repertoire as patients requested them. She suggests trying to expand your program by 10 percent each year, which she promises is achievable. Eventually you may grow your pharmacy into a complete immunization destination. “It just has a way of continuing to grow if you’re doing a good job at it,” she said.

Before you get started, reach out to other health providers and public health staff in your community, Rothholz said. “Identify what are their and their patients’ needs and challenges related to immunizations that your pharmacy could help address.”

Six Steps to Get Your Program Off the Ground

1. Check laws and regulations
2. Get trained and certified
3. Talk to other providers to get buy-in, discover needs, and establish a CPA if necessary
4. Prepare the pharmacy: create a private space, train staff, order supplies, and put a sign on the door
5. Establish workflow
6. Market the service

Potential Challenges

The biggest obstacle to getting an immunization program off the ground will likely be the legal aspect. Although every state allows pharmacists to administer vaccines, scope of authority varies widely. “The variability in what pharmacists can administer is typically dependent upon the age of the patient, the type of antigens or vaccine, and some other procedural modifications,” Rothholz said.

In many states, you have to establish standing protocols or collaborative practice agreements to be able to vaccinate. Most states require pharmacists to complete training on pharmacy-based immunizations. Pharmacies and pharmacists can check with their state pharmacy association or state board of pharmacy to identify the requirements and restrictions related to immunizations before getting started, Rothholz said.

If you need an agreement or protocol, Schaefer recommends coming up with a plan to approach a provider. Choose your provider carefully, maybe starting with the health department. And when you go to make your case, make it all about the patient. “Always, always take the high road,” she said. “It’s about giving patients easy access to preventive care.”

Another potential hurdle you’ll want to be ready for is billing. Coverage for vaccines in pharmacies varies from plan to plan, including some under Medicare Part B and others through Part D. Some plans cover the total cost of the vaccine, others require a copay, and others don’t cover it at all. If a vaccine is not covered under the patient’s pharmacy benefit, Feltner and Schaefer have the patient pay out-of-pocket and self-submit the claim to their medical insurance. However, pharmacies can enroll as a mass-immunization provider and be compensated at the same level as physicians and other providers under Medicare Part B, Rothholz said.

For pharmacies feeling overwhelmed by the thought of starting a program, there are all kinds of resources to help. Start with the APhA’s certification program, which has trained more than 340,000 pharmacists. “The program is now considered the gold standard for pharmacy-based immunizations. It’s updated, it’s in line with CDC recommendations, it’s reviewed by immunization experts, and it’s recognized by individuals outside of the profession for its quality and content,” Rothholz said. In addition, APhA provides access to products and resources to keep up with current recommendations and vaccine information.

For clinical and logistical resources, visit the Immunization Action Coalition (IAC) website (*www.immunize.org*), which provides protocols, vaccine information statements, consent forms, and a host of other free documents as well as complete guidelines for offering immunizations at the pharmacy. Further resources for everything you need can be found from the APhA, CDC, and the Advisory Committee on Immunization Practices (ACIP).

More Than Profit

One of Feltner's favorite parts of immunizations is the opportunity they provide to interact with patients. It's one of the few things that frees him from behind the counter to get that personal touch.

Same goes for Schaefer. "Doing an immunization, it's a very intimate and private moment," she said. "You actually get to know these patients in a different way than you do transacting over the counter."

Immunizations live in that sweet spot of pharmacy practice where healthier patients and a healthier business meet. Research overwhelmingly shows that when pharmacies vaccinate, uptake increases, outcomes improve, and healthcare costs decrease.

"The more often we vaccinate, the more chances we have to decrease disease," Feltner said. "And that's the whole goal is to vaccinate as many people as we can. And it's a great feeling as a pharmacist to immunize someone against a potentially deadly disease."

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20 Tips to Make Your Immunization Program a Profit Center

Maximize your profit by increasing immunization sales with smart strategies from pharmacy owners who have been doing it for decades. Independent pharmacy owner Beverly Schaefer and director of immunization services Marty Feltner provide tens of thousands of immunizations every year, and their independent pharmacies have become immunization destinations. Use these tips compiled from their expertise and current research to get most money from your immunization program.

1. Start the Conversation

Starting the conversation is the most important part of increasing immunizations, Schaefer said. “There’s lots of topics that you can choose to start a conversation about immunization—travel, staying healthy, new vaccines. Even if people don’t do it right then, it plants a seed in their brain. And it gets word-of-mouth going.”

2. Put a Sign on the Door

For Schaefer, a simple sign is the first and most important step in marketing your services. This has been her single most successful strategy for increasing immunizations. On the sign, list all the immunizations you offer. “When we did this, people were totally amazed that we were doing all these shots,” she said.

3. Educate Patients

According to the CDC, education remains the largest barrier to immunization coverage. Simply informing patients about the preventable diseases and the vaccines that prevent them is an easy way to increase immunization rates. Use in-store signage, brochures from manufacturers, bag inserts, or a conversation.

4. Make Specific Recommendations

Asking the right patients about the right vaccines will give you a higher conversion rate. That involves identifying eligible patients and recommending the specific vaccine to them directly. For example, if the patient is over 50, simply let them know: Nearly 40 percent of people who have had chickenpox will get shingles. Offer to give them the vaccine right then and there.

5. Target Flu Shot Patients

Patients who get the flu shot have already shown an openness to immunizations, which means they’ll be much more inclined to accept further vaccines, according to a 2018 study published in Psychological Science in the Public Interest (PSPI). When patients come in for flu shots, have them fill out an intake form and ask about the last time they received other recommended vaccines.

6. Make Strong Recommendations

The PSPI study also discovered that a strong recommendation from the provider is the single most powerful way to motivate someone to get vaccinated. Instead of asking if they would like the vaccine, tell them they're eligible and that they can get it before they leave the pharmacy.

7. Identify Eligible Patients

Most pharmacy systems allow you to create an alert for patients when their profile matches a vaccine need, which most often is based on age. Feltner relies on his employees to know which patients to look for and when to recommend vaccines. "The big key is to delegate and to train your staff on how to recognize someone who is eligible," he said. "Train your staff. Train your staff. Train your staff."

8. Utilize Entire Staff

After a visit to a national chain, Feltner realized how effective it is to have every single staff member, no matter their role, ask patients if they've gotten a vaccine. The store's cashier asked every patient at checkout if they had gotten the flu shot. If they said no, she directed them to the pharmacy. "I thought that was eye opening," he said. "That's part of the whole idea of delegating to your entire staff."

9. Zero Copay Tactic

This trick has been wildly successful for Feltner: He keeps track of which insurance and government plans offer patients a zero copay for a vaccine. Any time his staff sees a patient with one of those plans, they make the recommendation and let the patient know the vaccine is completely free. At that point, it's an easy sell.

10. Co-administration

Co-administering vaccines can also cause an uptick in vaccinations. Patients will be much more likely to receive multiple immunizations if they get them all in one stop rather than returning at another time. As long as the vaccines don't have contraindications, you can safely administer multiple vaccines in one visit. Also consider ordering combination vaccines that contain multiple vaccines in one shot, which are even more convenient for patients and reduce your storage costs.

11. Offsite Events

“Pharmacists who are successful in immunizations are not limiting provision of vaccines to the walls of their practice,” said Mitch Rothholz, chief strategy offer at APhA.“They’re going out to businesses and doing immunizations in the community, whether it be an event or in private businesses.” Offsite events not only generate money from vaccines given at the event, they’re also a perfect opportunity to recruit new patients to your pharmacy for good. Good offsite opportunities include school systems, health fairs, local businesses, assisted-living communities, apartment-complex communities, police departments, churches, and colleges.

12. Employer Partnerships

A huge source of immunization revenue for Feltner’s practice site is corporate partnerships. He’s developed relationships with several corporations who send their employees overseas. All of those employees go to Kohll’s Pharmacy for travel immunizations, which usually involve multiple vaccines.

13. On-Air Advertising

Go live on the radio or TV and give flu shots. “Just make it fun,” Feltner said. “The big thing I tell pharmacists is make it fun. Then you’re having fun immunizing and preventing disease.”

14. Helping with Costs

The second biggest barrier to immunizations, according to the CDC, is cost. The agency recommends pharmacies consult with local and state public health vaccination programs to learn about publicly funded programs that could help patients with the cost of vaccines. You can also enroll in the Vaccines for Children Program, which provides pharmacies federally purchased vaccines to fully vaccinate eligible children.

15. Offer Coupons

Take a page from the national chain pharmacies and big-box stores. Give patients a small voucher or coupon to your front end when they get an immunization from you. The profit you earn from them will outweigh the gift.

16. Fax Physicians

After immunizing a patient, Schaefer sends a fax to the provider. The fax includes the entire list of vaccines she offers, with an X next to the vaccine she administered. That way, the physician will know every vaccine she offers and can refer patients to her in the future.

17. Word-of-Mouth

If you offer a top-notch immunization program, your patients and physicians will do the advertising for you. Both Schaefer and Feltner attributed their most successful marketing to word-of-mouth. In fact, Schaefer spends zero dollars on advertising.

18. Answering Machine

Use your answering machine to highlight your immunization services. “When you call my store, it’s ‘Hello, you’ve reached Katterman’s pharmacy, your immunization destination,’” Schaefer said. “That way they’re thinking about immunizations whether they want to or not.”

19. Incentivize Your Pharmacists

Schaefer said the high margins on immunizations allow you to pay a bonus to your pharmacists for each immunization they administer. For an immunization that earns $20, let your pharmacists take two to five bucks of that to give them extra motivation.

20. Travel Tricks

Travel vaccinations come with their own bag of tricks—all of which genuinely help the health of patients.

- Hold a consultation with patients to ask where they're going, review their immunization history, and offer them everything they'll need.
- Use Travax, an online resource, to identify every vaccine a patient will need for the area they're visiting.
- Create a "travel checklist" with OTC items patients may need for the trip, which they can purchase in your front end.
- Compile a section in the front end dedicated solely to travel products and walk your patient through it after each consultation. Schaefer said it's not uncommon for patients to spend an extra one to two hundred dollars on her OTC travel products.
- Put a sign on your front door: "Are you traveling out of the country? Have you had your hep A, yellow fever, and typhoid shots?"
- If a patient comes in asking for a specific travel vaccination, ask where they're traveling. You may be able to offer additional immunizations or travel products.
- Get a standing order or collaborative practice agreement to administer prescription travel medicine, like antimalarial drugs.

From the Magazine

This article was published in our quarterly print magazine, which covers relevant topics in greater depth featuring leading experts in the industry. Subscribe to receive the quarterly print issue in your mailbox. All registered independent pharmacies in the U.S. are eligible to receive a free subscription.

Read more articles from the March issue:

- How CPESN networks break pharmacies into the lucrative side of healthcare
- A classic retail tactic that boosts front-end sales
- Is pharmacist prescribing authority on the rise?
- This pharmacy dramatically expanded its business through telepharmacy
- How to hire the best people for your pharmacy
- A new weight loss program that helps patients lose pounds

A Member-Owned Company Serving Independent Pharmacies

PBA Health is dedicated to helping independent pharmacies reach their full potential on the buy-side of their business. Founded and owned by pharmacists, PBA Health serves independent pharmacies with group purchasing services, wholesaler contract negotiations, proprietary purchasing tools, and more.

An HDA member, PBA Health operates its own NABP-accredited secondary wholesaler with more than 6,000 SKUs, including brands, generics, narcotics CII-CV, cold-storage products, and over-the-counter (OTC) products — offering the lowest prices in the secondary market.

SB372-INFO-Pharmacy Chaos.pdf
Uploaded by: MEGAN MONTGOMERY
Position: UNF

How Chaos at Chain Pharmacies Is Putting Patients at Risk

Pharmacists across the U.S. warn that the push to do more with less has made medication errors more likely. “I am a danger to the public,” one wrote to a regulator.

Published Jan. 31, 2020Updated Oct. 13, 2021

Video by Jeremy M. Lange For The New York Times

For Alyssa Watrous, the medication mix-up meant a pounding headache, nausea and dizziness. In September, Ms. Watrous, a 17-year-old from Connecticut, was about to take another asthma pill when she realized CVS had mistakenly given her blood pressure medication intended for someone else.

Edward Walker, 38, landed in an emergency room, his eyes swollen and burning after he put drops in them for five days in November 2018 to treat a mild irritation. A Walgreens in Illinois had accidentally supplied him with ear drops — not eye drops.

For Mary Scheuerman, 85, the error was discovered only when she was dying in a Florida hospital in December 2018. A Publix pharmacy had dispensed a powerful chemotherapy drug instead of the antidepressant her doctor had prescribed. She died about two weeks later.

The people least surprised by such mistakes are pharmacists working in some of the nation's biggest retail chains.

In letters to state regulatory boards and in interviews with The New York Times, many pharmacists at companies like CVS, Rite Aid and Walgreens described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs safely, putting the public at risk of medication errors.

They struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients and call doctors and insurance companies, they said — all the while racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less.

"I am a danger to the public working for CVS," one pharmacist wrote in an anonymous letter to the Texas State Board of Pharmacy in April.

"The amount of busywork we must do while verifying prescriptions is absolutely dangerous," another wrote to the Pennsylvania board in February. "Mistakes are going to be made and the patients are going to be the ones suffering."

[Read how you can protect yourself against medication errors.]

State boards and associations in at least two dozen states have heard from distraught pharmacists, interviews and records show, while some doctors complain that pharmacies bombard them with requests for refills that patients have not asked for and should not receive. Such refills are closely tracked by pharmacy chains and can factor into employee bonuses.

Michael Jackson, chief executive of the Florida Pharmacy Association, said the number of complaints from members related to staffing cuts and worries about patient safety had become "overwhelming" in the

past year.

CVS Health ranks eighth on the Fortune 500 list and has nearly 10,000 pharmacies across the United States.Jeenah Moon for The New York Times

The American Psychiatric Association is particularly concerned about CVS, America's eighth-largest company, which it says routinely ignores doctors' explicit instructions to dispense limited amounts of medication to mental health patients. The pharmacy's practice of providing three-month supplies may inadvertently lead more patients to attempt suicide by overdosing, the association said.

"Clearly it is financially in their best interest to dispense as many pills as they can get paid for," said Dr. Bruce Schwartz, a psychiatrist in New York and the group's president.

A spokesman for CVS said it had created a system to address the

issue, but Dr. Schwartz said complaints persisted.

Regulating the chains — five rank among the nation's 100 largest companies — has proved difficult for state pharmacy boards, which oversee the industry but sometimes allow company representatives to hold seats. Florida's nine-member board, for instance, includes a lawyer for CVS and a director of pharmacy affairs at Walgreens.

Aside from creating potential conflicts of interest, the industry presence can stifle complaints. "We are afraid to speak up and lose our jobs," one pharmacist wrote anonymously last year in response to a survey by the Missouri Board of Pharmacy. "PLEASE HELP."

Officials from several state boards told The Times they had limited authority to dictate how companies ran their businesses. Efforts by legislatures in California and elsewhere have been unsuccessful in substantially changing how pharmacies operate.

A majority of state boards do not require pharmacies to report errors, let alone conduct thorough investigations when they occur. Most investigations focus on pharmacists, not the conditions in their workplaces.

In public meetings, boards in at least two states have instructed pharmacists to quit or speak up if they believe conditions are unsafe. But pharmacists said they feared retaliation, knowing they could easily be replaced.

The industry has been squeezed amid declining drug reimbursement rates and cost pressures from administrators of prescription drug plans. Consolidation, meanwhile, has left only a few major players. About 70 percent of prescriptions nationwide are dispensed by chain

drugstores, supermarkets or retailers like Walmart, according to a 2019 Drug Channels Institute report.

CVS garners a quarter of the country's total prescription revenue and dispenses more than a billion prescriptions a year. Walgreens captures almost 20 percent. Walmart, Kroger and Rite Aid fall next in line among brick-and-mortar stores.

In statements, the pharmacy chains said patient safety was of utmost concern, with staffing carefully set to ensure accurate dispensing. Investment in technology such as e-prescribing has increased safety and efficiency, the companies said. They denied that pharmacists were under extreme pressure or faced reprisals.

"When a pharmacist has a legitimate concern about working conditions, we make every effort to address that concern in good faith," CVS said in a statement. Walgreens cited its confidential employee hotline and said it made "clear to all pharmacists that they should never work beyond what they believe is advisable."

Errors, the companies said, were regrettable but rare; they declined to provide data about mistakes.

The National Association of Chain Drug Stores, a trade group, said that "pharmacies consider even one prescription error to be one too many" and "seek continuous improvement." The organization said it was wrong to "assume cause-effect relationships" between errors and pharmacists' workload.

The specifics and severity of errors are nearly impossible to tally. Aside from lax reporting requirements, many mistakes never become public because companies settle with victims or their families, often requiring

a confidentiality agreement. A CVS form for staff members to report errors asks whether the patient is a “media threat,” according to a photo provided to The Times. CVS said in a statement it would not provide details on what it called its “escalation process.”

A CVS form for pharmacy staff members to report errors asks whether the patient is a “media threat.”

The last comprehensive study of medication errors was over a decade ago: The Institute of Medicine estimated in 2006 that such mistakes harmed at least 1.5 million Americans each year.

Jonathan Lewis said he waited on hold with CVS for 40 minutes last summer, after discovering his antidepressant prescription had been refilled with another drug.

Mr. Lewis, 47, suspected something was wrong when he felt short of breath and extremely dizzy. Looking closely at the medication — and turning to Google — he figured out it was estrogen, not an antidepressant, which patients should not abruptly quit.

“It was very apparent they were very understaffed,” Mr. Lewis said, recalling long lines inside the Las Vegas store and at the drive-through when he picked up the prescription.

Pharmacists have written to state regulatory boards about their safety concerns.

Too Much, Too Fast

The day before Wesley Hickman quit his job as a pharmacist at CVS, he worked a 13-hour shift with no breaks for lunch or dinner, he said.

As the only pharmacist on duty that day at the Leland, N.C., store, Dr.

Hickman filled 552 prescriptions — about one every minute and 25 seconds — while counseling patients, giving shots, making calls and staffing the drive-through, he said. Partway through his shift the next day, in December 2018, he called his manager.

Wesley Hickman, who now runs an independent pharmacy, left a job at CVS because of conditions he described as unsafe.Jeremy M. Lange for The New York Times

“I said, ‘I am not going to work in a situation that is unsafe.’ I shut the door and left,” said Dr. Hickman, who now runs an independent pharmacy.

Dr. Hickman felt that the multitude of required tasks distracted from his most important jobs: filling prescriptions accurately and counseling patients. He had begged his district manager to schedule more pharmacists, but the request was denied, he said.

CVS said it could not comment on the “individual concerns” of a former employee.

With nearly 10,000 pharmacies across the country, CVS is the largest chain and among the most aggressive in imposing performance metrics, pharmacists said. Both CVS and Walgreens tie bonuses to achieving them, according to company documents.

Editors’ Picks

[Sarah Polley Is OK With Oversharing]

[Feb. 17, 2022]

[‘The Batman’ Review: Who’ll Stop the Wayne?]

Nearly everything is tracked and scrutinized: phone calls to patients, the time it takes to fill a prescription, the number of immunizations given, the number of customers signing up for 90-day supplies of medication, to name a few.

The fact that tasks are being tracked is not the problem, pharmacists say, as customers can benefit from services like reminders for flu shots and refills. The issue is that employees are heavily evaluated on hitting targets, they say, including in areas they cannot control.

In Missouri, dozens of pharmacists said in a recent survey by the state board that the focus on metrics was a threat to patient safety and their own job security.

“Metrics put unnecessary pressure on pharmacy staff to fill prescriptions as fast as possible, resulting in errors,” one pharmacist wrote.

Of the nearly 1,000 pharmacists who took the survey, 60 percent said they “agree” or “strongly agree” that they “feel pressured or intimidated to meet standards or metrics that may interfere with safe patient care.” About 60 percent of respondents worked for retail chains, as opposed to hospitals or independent pharmacies.

Surveys in Maryland and Tennessee revealed similar concerns.

The specific goals are not made public, and can vary by store, but internal CVS documents reviewed by The Times show what was expected in some locations last year.

Staff members were supposed to persuade 65 percent of patients picking up prescriptions to sign up for automatic refills, 55 percent to

switch to 90-day supplies from 30-day, and 75 percent to have the pharmacy contact their doctor with a “proactive refill request” if a prescription was expiring or had no refills, the documents show.

Prescriptions at Dr. Hickman's pharmacy. When he worked at CVS, he said, longtime patients sometimes signed up for automatic refills as a favor to help him meet corporate metrics.Jeremy M. Lange for The New York Times

Pharmacy staff members are also expected to call dozens of patients each day, based on a computer-generated list. They are assessed on the number of patients they reach, and the number who agree to their requests.

Representatives from CVS and Walgreens said metrics were meant to provide better patient care, not penalize pharmacists. Some are related to reimbursements to pharmacies by insurance companies and the government. CVS said it had halved its number of metrics over the past 18 months.

But dozens of pharmacists described the emphasis on metrics as burdensome, and said they faced backlash for failing to meet the goals or suggesting they were unrealistic or unsafe.

“Any dissent perceived by corporate is met with a target placed on one’s back,” an unnamed pharmacist wrote to the South Carolina board last year.

In comments to state boards and interviews with The Times, pharmacists explained how staffing cuts had led to longer shifts, often with no break to use the restroom or eat.

“I certainly make more mistakes,” another South Carolina pharmacist wrote to the board. “I had two misfills in three years with the previous

staffing and now I make 10-12 per year (that are caught)."

Much of the blame for understaffing has been directed at pressure from companies that manage drug plans for health insurers and Medicare.

Acting as middlemen between drug manufacturers, insurers and pharmacies, the companies — known as pharmacy benefit managers, or P.B.M.s — negotiate prices and channel to pharmacies the more than $300 billion spent on outpatient prescription drugs in the United States annually.

The benefit managers charge fees to pharmacies, and have been widely criticized for a lack of transparency and applying fees inconsistently. In a letter to the Department of Health and Human Services in September, a bipartisan group of senators noted an "extraordinary 45,000 percent increase" in fees paid by pharmacies from 2010 to 2017.

While benefit managers have caused economic upheaval in the industry, some pharmacy chains are players in that market too: CVS Health owns CVS Caremark, the largest benefit manager; Walgreens Boots Alliance has a partnership with Prime Therapeutics; Rite Aid owns a P.B.M., too.

Walgreens draws nearly 20 percent of the United States' total prescription revenue.Jeenah Moon for The New York Times

The Pharmaceutical Care Management Association, the trade group representing benefit managers, contends that they make prescriptions more affordable, and pushes back against the notion that P.B.M.s are responsible for pressures on pharmacies, instead of a competitive

market.

Pharmacists have written to state regulatory boards about their safety concerns.

Falling Through the Cracks

Dr. Mark Lopatin, a rheumatologist in Pennsylvania, says he is inundated with refill requests for almost every prescription he writes. At times Dr. Lopatin prescribes drugs intended only for a brief treatment — a steroid to treat a flare-up of arthritis, for instance.

But within days or weeks, he said, the pharmacy sends a refill request even though the prescription did not call for one. Each time, his office looks at the patient's chart to confirm the request is warranted. About half are not, he said.

Aside from creating unnecessary work, Dr. Lopatin believes, the flood of requests poses a safety issue. "When you are bombarded with refill after refill, it's easy for things to fall through the cracks, despite your best efforts," he said.

Pharmacists told The Times that many unwanted refill requests were generated by automated systems designed in part to increase sales. Others were the result of phone calls from pharmacists, who said they faced pressure to reach quotas.

In February, a CVS pharmacist wrote to the South Carolina board that cold calls to doctors should stop, explaining that a call was considered "successful" only if the doctor agreed to the refill.

"What this means is that we are overwhelming doctor's office staff with

constant calls, and patients are often kept on medication that is unneeded for extended periods of time," the pharmacist wrote.

CVS says outreach to patients and doctors can help patients stay up-to-date on their medications, and lead to lower costs and better health.

Dr. Rachel Poliquin, a psychiatrist in North Carolina who says she constantly gets refill requests, estimates that about 90 percent of her patients say they never asked their pharmacy to contact her.

While Dr. Poliquin has a policy that patients must contact her directly for more medication, she worries about clinics where prescriptions may get rubber-stamped in a flurry of requests. Then patients — especially those who are elderly or mentally ill — may continue taking medication unnecessarily, she said.

The American Psychiatric Association has been trying to tackle a related problem after hearing from members that CVS was giving patients larger supplies of medication than doctors had directed.

While it is common for pharmacies to dispense 90 days' worth of maintenance medications — to treat chronic conditions like high blood pressure or diabetes — doctors say it is inappropriate for other drugs.

For example, patients with bipolar disorder are often prescribed lithium, a potentially lethal drug if taken in excess. It is common for psychiatrists to start a patient on a low dose or to limit the number of pills dispensed at once, especially if the person is considered a suicide risk.

But increasingly, the psychiatric association has heard from members that smaller quantities specified on prescriptions are being ignored,

particularly by CVS, according to Dr. Schwartz, the group's president.

CVS has created a system where doctors can register and request that 90-day supplies not be dispensed to their patients. But doctors report that the registry has not solved the problem, Dr. Schwartz said. In a statement, CVS said it continued to "refine and enhance" the program.

Dr. Charles Denby, a Rhode Island psychiatrist, said CVS ignored his explicit directions not to dispense 90-day supplies of medication to patients.Tony Luong for The New York Times

Even after he began stamping the instructions on prescriptions, he said, CVS would tell him the "baldfaced lie" that his patients were asking for 90-day supplies. Dr. Denby's D.E.A. number has been redacted.Tony Luong for The New York Times

Dr. Charles Denby, a psychiatrist in Rhode Island, became so concerned by the practice that he started stamping prescriptions, "AT MONTHLY INTERVALS ONLY." Despite those explicit instructions, Dr. Denby said, he received faxes from CVS saying his patients had asked for — and been given — 90-day supplies.

Dr. Denby, who retired in December, said it was a "baldfaced lie" that the patients had asked for the medication, providing statements from patients saying as much.

"I am disgusted with this," said Dr. Denby, who worries that patients may attempt suicide with excess medication. "There are going to be people dead only because they have enough medication to do the deed with."

'We Already Have Systems in Place'

Alton James never learned how the mistake came about that he says killed his 85-year-old mother, Mary Scheuerman, in 2018.

He knows he picked up her prescription at the pharmacy in a Publix supermarket in Lakeland, Fla. He knows he gave her a pill each morning. He knows that after six days, she turned pale, her blood pressure dropped and she was rushed to the hospital.

Mary Scheuerman died in December 2018 after taking a powerful chemotherapy drug mistakenly dispensed by a Publix pharmacy. Her son said she was supposed to have received an antidepressant.

Mr. James remembers a doctor telling him his mother's blood had a toxic level of methotrexate, a drug often used to treat cancer. But Mrs. Scheuerman didn't have cancer. She was supposed to be taking an antidepressant. Mr. James said a pharmacy employee later confirmed that someone had mistakenly dispensed methotrexate.

Five days after entering the hospital, Mrs. Scheuerman died, with organ failure listed as the lead cause, according to medical records cited by Mr. James.

The Institute for Safe Medication Practices has warned about methotrexate, listing it as a "high-alert medication" that can be deadly when taken incorrectly. Mr. James reported the pharmacy's error to the group, writing that he wanted to raise awareness about the drug and push Publix, one of the country's largest supermarket chains, to "clean up" its pharmacy division, according to a copy of his report provided to The Times.

Trexall, a brand name for the drug methotrexate, can be used to treat cancer.

The company acknowledged the mistake and offered a settlement, Mr. James wrote, but would not discuss how to avoid future errors, saying, "We already have systems in place."

Last September, Mr. James told The Times that Publix wanted him to

sign a settlement agreement that would prevent him from speaking further about his mother's death. Mr. James has since declined to comment, saying that the matter was "amicably resolved."

A spokeswoman for Publix said privacy laws prevented the company from commenting on specific patients.

It can be difficult for patients and their families to decide whether to accept a settlement.

Last summer, CVS offered to compensate Kelsey and Donavan Sullivan after a pediatrician discovered the reflux medication they had been giving their 4-month-old for two months was actually a steroid. To be safely weaned, the baby had to keep taking it for two weeks after the error was discovered.

"It was like he was coming out of a fog," Mrs. Sullivan recalled.

Kelsey and Donavan Sullivan with their son, Finnegan. Last year, a CVS mistakenly dispensed a steroid for the baby in place of reflux medication. Nina Robinson for The New York Times

The couple, from Minnesota, are still considering a settlement but haven't agreed to anything because they don't know what long-term consequences their son might face.

The kinds of errors and how they occur vary considerably.

The paper stapled to a CVS bag containing medication for Ms. Watrous, the Connecticut teenager with asthma, listed her correct name and medication, but the bottle inside had someone else's name.

Directions on the prescription for Mr. Walker, the Illinois man who got ear drops instead of eye drops from Walgreens, were clear: "Instill 1

drop in both eyes every 6 hours." He later saw the box: "For use in ears only."

In September, Stefanie Davis, 31, got the right medicine, Adderall, but the wrong dose. She pulled over on the interstate after feeling short of breath and dizzy with blurred vision. The pills, dispensed by a Walgreens in Sun City Center, Fla., were each 30 milligrams instead of her usual 20. She is fighting with Walgreens to cover a $900 bill for her visit to an emergency room.

Fixes That Fall Short

State boards and legislatures have wrestled with how to regulate the industry. Some states have adopted laws, for instance introducing mandatory lunch breaks or limiting the number of technicians a pharmacist can supervise.

But the laws aren't always followed, can be difficult to enforce or can fail to address broader problems.

The National Association of Chain Drug Stores says some state boards are blocking meaningful change. The group, for instance, wants to free up pharmacists from some tasks by allowing technicians, who have less training, to do more.

It also supports efforts to change the insurance reimbursement model for pharmacies. Health care services provided by pharmacists to patients, such as prescribing birth control, are not consistently covered by insurers or allowed in all states. But it has been difficult to find consensus to change federal and state regulations.

While those debates continue, some state boards are trying to hold

companies more accountable.

For Mrs. Sullivan's infant to safely wean off the high-dose steroid he was given by mistake, he had to keep taking it for two weeks after the error was discovered.Nina Robinson for The New York Times

Often when an error is reported to a board, action is taken against the pharmacist, an obvious target. It is less common for a company to be scrutinized.

The South Carolina board discussed in November how to more thoroughly investigate conditions after a mistake. It also published a statement discouraging quotas and encouraging "employers to value patient safety over operational efficiency and financial targets."

California passed a law saying no pharmacist could be required to work alone, but it has been largely ignored since taking effect last year, according to leaders of a pharmacists' union. The state board is trying to clarify the law's requirements.

In Illinois, a new law requires breaks for pharmacists and potential penalties for companies that do not provide a safe working environment. The law was in response to a 2016 Chicago Tribune investigation revealing that pharmacies failed to warn patients about dangerous drug combinations.

Some states are trying to make changes behind closed doors. After seeing results of its survey last year, the Missouri board invited companies to private meetings early this year to answer questions about errors, staffing and patient safety.

CVS and Walgreens said they would attend.

Research was contributed by Susan C. Beachy, Jack Begg, Alain

SB372-INFO-Pharmacy Gave Children Wrong Shot Dose

Uploaded by: MEGAN MONTGOMERY

Position: UNF

Virginia Pharmacy Gave Wrong COVID Vaccine Dosage to Children 5-11

Ted Pharmacy In Loudoun County can no longer provide COVID-19 vaccines after health officials say more than 100 children were given the wrong dosage

By Cory Smith, News4 Reporter • Published November 10, 2021 • Updated on November 10, 2021 at 8:39 pm

NBC Universal, Inc.

The health department in Loudoun County began administering COVID-19 shots to children ages 5 to 11. News4's Justin Finch reports what parents in the area need to know.

A pharmacy in Loudoun County, Virginia, gave the wrong COVID-19 vaccine dosage to some children, worrying parents and leading health officials to send out a warning to families Wednesday.

Ted Pharmacy, located in a building on Stone Carver Drive in Aldie, admitted to giving children 5-11 a dose of the vaccine meant for people 12 years and older. The Virginia Department of Health said about 112 children in Loudoun County are affected.

Dasha Hermosilla told News4 a pharmacist at Ted Pharmacy gave her daughter, 7-year-old Gryffin Fahle, a diluted dose of the vaccine for people 12 and older, which comes in a vial with a purple cap, not the orange cap of the vaccine meant for younger children.

She said the pharmacist told them it was OK. But a simple Google search later confirmed Hermosilla's fear that it was not.

"Nothing says that you can change a purple to an orange," Hermosilla said. "I had this pit in my stomach that, like, what did they just do to my daughter?"

Hermosilla wasn't the only parent asking that question. Another mom sent News4 a screengrab of a Facebook conversation in which the pharmacy admitted to the mistake and apologized for the "inconvenience."

"The way they have dealt with individuals is really, like, 'Oh, it's no big deal,'" Hermosilla said. "There are dozens and dozens of families out there that don't even know that this is an issue."

State health officials told parents the Virginia Board of Pharmacy has opened an investigation, but the agency would neither confirm nor deny that when News4 inquired.

After News4's interview with Hermosilla, the Loudoun County Health Department released an alert about the pharmacy's error.

"The pharmacy who administered the Pfizer COVID-19 vaccination to your child last week has been removed from both state and federal COVID-19 vaccination programs," Loudoun County Department of Health Director David Goodfriend said in the letter.

The health department said parents of affected children should first consult with their child's pediatrician to decide the best course of action.

If a lower dosage of the vaccine meant for people 12 and older is given to younger children, parents can wait 21 days to restart the correct COVID-19 vaccine series, according to the Centers for Disease Control and Prevention.

Parents can either wait the 21 days or proceed with getting the second dose as scheduled, ensuring it is the correct vaccine with the orange cap, the county health department said.

Health officials also said parents should watch for side effects of the vaccine, such as fever, chills, fatigue and pain or redness at the injection site and call their pediatrician if their child has prolonged or more serious side effects.

Goodfriend said in the letter that Ted Pharmacy relinquished the rest of its COVID-19 vaccines to the health department.

Below is the full statement a spokesperson for Virginia's Board of Pharmacy gave News4:

Virginia's Board of Pharmacy (BOP) takes seriously the mission of the Department of Health Professions which is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.

It is important to note under Virginia law 54.1-2400.2, Virginia's health regulatory boards, including the Board of Pharmacy (BOP), are not at liberty to confirm nor deny whether an investigation into a possible violation of a law or regulation is or is not underway.

Should an investigation reveal there is probable cause to believe a law

or regulation was broken an Informal Conference or a Formal Hearing before the board may be held for consideration of possible disciplinary action. The Board's findings of fact and resulting actions are contained in a Board Order that becomes a matter of public record available online on the Board of Pharmacy's website under License Lookup and Recent Case Decisions.

BOP licenses and regulates approximately 75,000 practitioners and entities; inspects pharmacy facilities; manages practitioner and patient registration for the use of medical cannabis and regulates the state's five pharmaceutical processor permit holders.

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Uploaded by: MEGAN MONTGOMERY

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SB372-INFO-Shots Given Incorrectly (1).pdf
Uploaded by: MEGAN MONTGOMERY
Position: UNF

Half of All New Federal Vaccine Cases Allege Injury From Shots Given Incorrectly

By Jodie Fleischer, News4 I-Team Reporter, Rick Yarborough and Jeff Piper • Published May 1, 2018 • Updated on May 2, 2018 at 7:05 pm

An I-Team review found half of all the new federal vaccine injury cases allege “shoulder injury resulting from vaccine administration,” or SIRVA, and have little or nothing to do with what was in the syringe. Jodie Fleischer reports.

After months of questioning by the News4 I-Team, two federal agencies have vowed to study injuries from vaccines alleged to have been given incorrectly.

An I-Team review found half of all the new federal vaccine injury cases allege “shoulder injury resulting from vaccine administration,” or SIRVA, and have little or nothing to do with what was in the syringe.

Both the Centers for Disease Control and the Health Resources and Services Administration previously told the I-Team there were no comprehensive studies of SIRVA underway, despite the relevant information being filed into thousands of court cases alleging that injury. The influx of new SIRVA cases has further hampered an already backlogged court system riddled with delays.

Those cases allege the shots were administered incorrectly — usually too high on the arm — but the I-Team found the program has no mechanism to notify the shot-giver of the injury he or she likely caused. Thus, they would have no reason to seek additional training.

'The Most Excruciating Pain I've Ever Had'

Ann Wyborski didn't think twice when her OB-GYN suggested she get her flu shot in 2013. She was nine months pregnant at the time.

"They swabbed the whole area," she told the News4 I-Team. "But as soon as [the needle] went in I said, 'That's too high.'"

Wyborski says by the time she got to her car, she struggled to put on her seatbelt. She couldn't type on her keyboard at work or do anything around the house.

"It was a throbbing constant pain — the most excruciating pain I've ever had," she said.

About a week later she went into labor and gave birth to her baby boy. She had trouble nursing and even holding him.

"I realized there was a massive problem because I had just had major surgery and I was crying about the pain in my arm, not from my C-section," she said.

She went to her doctor and an orthopedic specialist, but they didn't know what was causing her pain. They even sent her to physical therapy, which Wyborski says worsened her condition.

She was suffering from SIRVA.

"The person administered the shot in the wrong spot, is basically what happens — usually too high on the arm," explained Renee Gentry, who runs the Vaccine Injury Law Clinic at George Washington University.

Gentry says SIRVA has become so common; it's now covered under the

National Vaccine Injury Compensation Program — a nearly $3.7 billion trust fund created and run by the federal government to take care of victims with catastrophic reactions to vaccines.

"Vaccines have been an extraordinary contribution to society," said Gentry, "but they're not magic. They are pharmaceuticals, and anyone can react to them."

To keep companies developing and producing vaccines, the government took on the liability back in the late 1980s, protecting vaccine-makers and those who give the shots from being sued.

The Vaccine Court

Instead, these cases go through a special vaccine court inside the U.S. Court of Federal Claims.

In a traditional lawsuit, the victim would usually have to show negligence, not just that the vaccine caused the injury within a certain timeframe.

More than 80 percent of all compensation awards in the vaccine court are negotiated settlements, which allows the government to include language stating it has not concluded, based on the review of the evidence, that the vaccine caused the injury.

A $0.75 tax on every shot given funds the vaccine compensation. Since the program started, about 6,000 victims have received nearly $4 billion.

"It has good intentions and it means well, it's just not being implemented correctly," said Martha Toomey, a parent of a vaccine-

injured child.

It took Toomey more than a decade to get compensated after her son, Jeffrey, started having seizures within 24 hours of getting a vaccine. She says he ended up with a traumatic brain injury and a lifetime of health problems.

"There are a lot of words in the English language," said Toomey, "but I can't think of anything that would describe that kind of hell."

Hers is the kind of family the Vaccine Court was designed to help, but the program now has five times the number of cases it had in 2011, and Congress has never increased the number of judges allowed to hear them.

"Right now, the earliest available hearing date is in 2020," said Gentry.

The U.S. Department of Health and Human Services declined the I-Team's request for an on-camera interview.

But after a month of questioning, the agency finally acknowledged half of all the new cases filed in the court last year were not vaccine reactions — they were SIRVA cases.

"It's frustrating, I think, for everyone involved in it, because it's preventable," said Gentry.

‘You Can't Make Informed Decisions If You Don't Have The Information’

And the I-Team discovered no one keeps data on how often SIRVA happens, where it's happening or even which shot-givers caused the injury. So they're never told to improve their technique, which Wyborski

calls ridiculous. She says a temporary nurse from her doctor's office gave her the shot.

"Once an injury happens, they need to follow up and make sure that person doesn't continually injure more people," Wyborski said.

In a statement to the News4 I-Team, HHS admitted it "does not track or monitor this data" — despite the info being filed in to the record with every vaccine court case.

"Somebody at HHS has to say, 'I'm going to take control of this and I'm going to fix it,'" said Toomey, who also serves on a vaccine advisory commission, which recommended Congress double the number of judges for the program in 2016.

HHS has asked for increased funding for the program each year but told the I-Team "as to the allocation of the requested funding, this is a question for the Congress."

"Yes, Congress should look at this," Maryland Sen. Chris Van Hollen told the I-Team.

Van Hollen pointed out that the benefits of getting vaccines still far outweigh the risks, but he says SIRVA is definitely something federal agencies should be tracking.

"We need to collect the data," said Sen. Van Hollen, "because you can't make informed decisions if you don't have the information to start with."

A review by the News 4 I-Team found the Vaccine Injury Compensation Program has paid 575 SIRVA patients more than $76 million while doing

little to fight the problem.

"If you don't inform the people who are doing it wrong, they're not going to learn to do it right," said Van Hollen.

Shot-Givers Aren't Told About Injuries They Likely Caused

The Health Resources and Services Administration is the HHS agency that oversees this program.

A HRSA spokesperson told the I-Team a confidentiality provision in the program prohibits the agency from notifying the vaccine administrator of the corresponding SIRVA case.

Because they are protected from liability, the shot-giver is not a party to the lawsuit, so each SIRVA victim would have to give written consent to allow them to be told about the vaccine injury they likely caused.

When the I-Team asked what's being done to combat the drastic rise in SIRVA cases, HRSA suggested contacting the Centers for Disease Control and Prevention. (Read our entire exchange of questions and answers with HRSA here.)

The CDC says the increase in the number of SIRVA cases could be because more people are getting shots or because more people are aware of SIRVA and reporting it.

Each state decides which medical professionals are allowed to administer vaccines and the training required; some have relaxed their rules over time to make vaccines readily accessible to the public.

The CDC has launched an educational campaign on the correct way to administer shots. They're supposed to be given in the deltoid muscle,

the thick part of the upper arm, but not too close to the shoulder.

In January, a representative from the CDC's Immunization Safety Office told the I-Team it had no comprehensive data on SIRVA occurrences and no immediate plans to do any further investigation.

He had conducted a partial study of voluntary reports submitted to a separate system called VAERS, the Vaccine Adverse Event Reporting System. The CDC found most of the SIRVA injuries reported happened after vaccines were administered at pharmacies or stores but cautioned that that system doesn't verify the injury or identify its cause.

Just last week, the CDC told the I-Team it will now work together with HRSA to conduct an epidemiologic review of the SIRVA claims in the Vaccine Injury Compensation Program, which they're hoping to complete by the end of 2019.

"I think it needs to be fixed," said Wyborski, who got a settlement from the program for her pain and suffering, medical costs, and lost wages.

She says no amount of money is worth what she went through.

"I spent over 18 months in excruciating pain," she said. "You can't get that back."

Reported by Jodie Fleischer, produced by Rick Yarborough, and shot and edited by Jeff Piper.

SB372-MandatedReport1-2021.pdf
Uploaded by: MEGAN MONTGOMERY
Position: UNF

Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

March 16, 2022

The Honorable Paul G. Pinsky, Chair
Education, Health and Environmental Affairs Committee
Miller Senate Office Building, 2 West
Annapolis, MD 21401

The Honorable Shane E. Pendergrass, Chair, Health and Government Operations Committee
House Office Building, Room 241
Annapolis, MD 21401

Re: SB 736/HB 1040 (Chapters 792 and 793 of the Acts of 2021) - Health Occupations - Pharmacists - Administration of Children's Vaccines - Study and Temporary Authority

Dear Chairs Pinsky and Pendergrass:

Pursuant to Health Occupations - Pharmacists - Administration of Children's Vaccines - Study and Temporary Authority (HB 1040/SB 736) (2021), the Maryland Department of Health (MDH) is directed to produce a report, in consultation with the State Board of Pharmacy, to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee. In accordance with § 2–1257 of the State Government Article, MDH must include information it determines is important for setting policies for authorizing pharmacists to administer vaccinations to children, including: (1) the number of vaccines administered to children by pharmacists in accordance with the requirements of Section 1 of this Act; (2) the effectiveness and efficiency of ImmuNet; and (3) whether the option for children to be administered vaccines by pharmacists has led to changes in well-child visits with pediatric primary care providers.

Md. Ann. Code Health-General Article §18–109 requires an ImmuNet program. The current ImmuNet platform was implemented in 2010 as a database to capture and record an individual's vaccination records and provide a web-based tool for healthcare providers and schools to keep their patient and/or student vaccinations up-to-date. Health-General Article §§12-508 and 18–109, respectively, require pharmacists and local health departments to report all vaccinations to ImmuNet. In October 2019, HB 316 (2019) amended the law to require vaccinations administered by all providers in Maryland be reported to ImmuNet with the exception of those administered in nursing facilities, assisted living programs, continuing care retirement communities, or medical day care programs. Since its inception, ImmuNet has captured over 74 million vaccinations and has nearly 8,000 registered organizations throughout the state. Additionally, providers in the federal Vaccines for Children (VFC) program are required to order vaccinations for their VFC eligible population in ImmuNet. Since the capability to support this was developed, VFC providers have ordered over 16 million vaccinations. ImmuNet serves

as the primary source for COVID-19 vaccination data, and all doses of COVID-19 vaccinations are ordered through ImmuNet.

Table 1 provides the following data from all time as measurements of ImmuNet's overall efficiency and effectiveness in surveilling vaccinations in the state: the total number of vaccinations administered by pharmacists to children, vaccinations recorded in ImmuNet, organizations registered with ImmuNet, vaccinations ordered in ImmuNet, and the percentage of providers reporting to ImmuNet. In accordance with Health-General Article §12–508, pharmacists are required to report all vaccinations administered to ImmuNet.

Table 1: Total Vaccinations, Providers, and Organizations Reported to ImmuNet, Maryland, 2018-2020

Indicator	CY 18	CY 19	CY 20
Vaccinations administered to children by pharmacists (<18 years of age)	33,519	33,507	70,016
Vaccinations recorded in ImmuNet	4,667,683	4,885,797	4,733,823
Organizations in ImmuNet	3,924	4,154	6,138
Vaccinations ordered in ImmuNet	1,072,708	1,168,669	1,172,299
Percent of providers reporting to ImmuNet	66%	69%	47%

MDH's Prevention and Health Promotion Administration and Maryland Medicaid worked together to provide data on well-child visits with pediatric primary care providers prior to and after the enactment of this legislation. This data is presented in Table 2.

Table 2: Medicaid Enrollees Well-Care Visits and Vaccinations, Maryland, 2018-2020

Indicator	CY 18	CY 19	CY 20*
Total Enrollees	564,000	565,922	564,057
Enrollees with a Well-Care Visit	338,510	345,143	295,786
Enrollees with a Vaccination from a Non-Pharmacy Provider	231,551	230,044	206,086
Enrollees with a Well-Care Visit and a Vaccination from a Non-Pharmacy Provider	208,685	208,894	185,732
Enrollees with a Vaccination from a Pharmacy	5,701	5,108	10,913
Enrollees with a Well-Care Visit and a Vaccination from a Pharmacy	3,739	3,398	6,138
Enrollees with Any Vaccination	234,938	233,343	213,800
Enrollees with a Well-Care Visit and Any Vaccination	210,364	210,633	188,981

**Service utilization in CY20 may be impacted by the COVID-19 pandemic*

The results of an analysis of Medicaid data conducted by The Hilltop Institute show that enrollees receiving vaccinations from a pharmacy increased in number while those receiving vaccinations in other settings declined during the study period. However, it is important to note that providers may submit fee-for-service (FFS) claims for up to 12 months after the date of service. Therefore, an insufficient period has passed to gather all claims and encounters rendered

for the entire measurement period. Data for this period are considered preliminary at this time. Additionally, service utilization in calendar year 2020 may be impacted by the COVID-19 pandemic.

If you have questions about this report, please contact Heather Shek, Director, Office of Governmental Affairs, at 410-767-5282 or heather.shek@maryland.gov.

Sincerely,

Dennis R. Schrader
Secretary

cc: Jinlene Chan, MD, MPH, FAAP, Deputy Secretary, Public Health Services
Steven R. Schuh, MA, Deputy Director for Health Care Financing Administration and Medicaid Director
Heather Shek, JD, MS, Director, Office of Governmental Affairs
Donna Gugel, MHS, Director, Prevention and Health Promotion Administration
Deena Speights-Napata, MA, Executive Director, Maryland Board of Pharmacy
David Blythe, MD, MPH, Director, Infectious Disease Epidemiology and Outbreak Response Bureau
Sarah Albert, Department of Legislative Services, 5 copies (MSAR # 13347)

SB0372_UNF_MedChi, MDAAP, MACHC_Health Occs. - Pha

Uploaded by: Pam Kasemeyer

Position: UNF

The Maryland State Medical Society
63711 Cathedral Street
Baltimore, MD 263701-5516
410.539.0872
Fax: 410.547.0915
1.800.492.1056
www.medchi.org

TO: The Honorable Melony Griffith, Chair
Members, Senate Finance Committee
The Honorable Malcolm Augustine

FROM: Pamela Metz Kasemeyer
Danna L. Kauffman
J. Steven Wise
Andrew G. Vetter
Christine K. Krone
410-244-7000

DATE: February 28, 2023

RE: **OPPOSE UNLESS AMENDED** – Senate Bill 372 – *Health Occupations – Pharmacists – Administration of Vaccines*

On behalf of the Maryland State Medical Society, the Maryland Chapter of the American Academy of Pediatrics, and the Mid-Atlantic Association of Community Health Centers, we **oppose** Senate Bill 372, **unless the legislation is amended**.

Senate Bill 372 removes the sunset date, implemented as a result of legislation in 2021 during the COVID-19 public health crisis, which authorizes a pharmacist to administer a vaccination listed in the U.S. Centers for Disease Control and Prevention's (CDC) recommended immunization schedule to minors age 3 and older without a prescription. Prior to this change in law, a pharmacist was authorized to administer a vaccination to a minor age 11 and older only with a prescription from an authorized prescriber. CDC's recommended immunization schedule for persons 3 through 18 years old includes vaccinations for diphtheria, tetanus, and acellular pertussis (DTap); diphtheria and tetanus (DT); haemophilus influenza type B; hepatitis A; hepatitis B; human papillomavirus (HPV); influenza; measles, mumps, and rubella (MMR); meningococcal; pneumococcal; poliovirus; tetanus, diphtheria, and acellular pertussis (Tdap); tetanus and diphtheria (Td); and varicella, many of which require multiple doses.

Immunizations are an integral component of the delivery of pediatric services. Vaccines are essential to the health and well-being of our children and to the public health of the community. Maryland has historically had an outstanding record of immunization rates, one of the highest in the country. The above-named organizations understand that at the federal level, in August of 2020, in the midst of the COVID-19 public health crisis, the U.S. Department of Health and Human Services changed its policy and recognized pharmacists to vaccinate children 3 years and older. Subsequently, Maryland changed its law to be consistent with federal law. However, that change was reflective of a survey, which indicated many States' immunization rates were not nearly as high as Maryland's and influenced by the current public health emergency. There is no evidence of an unmet need, given the State's extraordinarily high vaccination rate and may have unintended negative consequences for the health of Maryland's children if the policy if continued.

Fragmentation of comprehensive medical care will be the outcome of the implementation of this legislation. There is a continuing and appropriate push to create "medical homes" and enhance the coordinated provision of comprehensive services with a focus on prevention, Senate Bill 372 moves in the opposite direction. A pharmacist will have no access to information about the child, no awareness of health conditions that may place the child at risk for the immunization, such as allergy or asthma, and no means to know if there are other services that a child needs that will not be provided because a parent believes immunizations were the only service a child required.

Pediatricians regularly use visits scheduled for immunizations to provide other critical preventative services. Parents often do not schedule visits for routine well-child care but may bring their child to the office for vaccines. At those visits, a pediatrician will often provide additional services, such as developmental screenings, behavioral health screenings, hearing and vision assessments, or counseling, and updates on management of chronic health concerns like asthma and obesity. These well-child visits are especially critical for children entering preschool and elementary school, not because of vaccination requirements but for school readiness screening and the identification of services that may be needed as the child enters school. Furthermore, with the added focus on behavioral health challenges faced by children and adolescents, as well as the recognition that sexual activity may also commence during adolescence, those visits also provide an opportunity for pediatric providers to screen for and discuss those issues with the adolescent. If a parent can simply take a child to a pharmacy for a vaccine, the opportunity for more comprehensive care will be lost. The fragmentation of care that will result from Senate Bill 372 will ultimately produce poorer outcomes and increased health care expenditures.

Furthermore, ImmuNet, the database that provides information on what immunizations have been administered is continually improving as a reliable tool, but it is still not without technical complications and lacks complete information. While all pharmacists and providers are required to enter all immunizations administered into ImmuNet, the database does not always reflect data entered and/or compliance with the mandate to report is not consistently adhered to. Aside from the arguments already raised, it is strongly recommended that before any consideration be given to authorize pharmacists to administer immunizations to minors without a prescription that functionality and completeness of ImmuNet be addressed collectively by all affected stakeholders. Absent a reliable and comprehensive database, a provider would not know if a minor received a vaccination from a pharmacist and parents' knowledge and recollection of what has been administered is not always complete, again leading to a fragmentation of the delivery of preventative care.

It is also of note that pharmacists are not Vaccine for Children (VFC) providers. VFC provides vaccines for administration for children who are covered by Medicaid or are uninsured. It is a critical program to ensure all children have access to vaccines, regardless of insurance coverage or an ability to pay. Unless pharmacists are VFC providers, the access to critical immunizations will further exacerbate access to necessary health care services by disadvantaged and minority communities, thereby increasing already existing health care disparities for this population.

The above-named organizations appreciate that there has been a loosening of vaccination administration authority during the COVID-19 public health crisis. To that end, they would support amendment of the legislation to retain the authority of pharmacists to administer COVID-19, flu, and any other vaccine developed to address a public health emergency. However, for permanent changes in vaccine administration policy for children for all other recommended vaccines, Senate Bill 372's enactment will only create problems, not address deficiencies in the current provision of immunizations for children and will further exacerbate the noted decline in well-child visits. An unfavorable report is requested unless the legislation is amended to limit the authorization only to COVID-19, flu, and vaccines developed to respond to a public health emergency.

Unfavorable SB372.pdf
Uploaded by: Peter DOrazio
Position: UNF

Hello Senate Finance Committee,

I am writing as a Maryland Registered Pharmacist to oppose SB372. There are several reasons why this bill should be pulled and not considered for enactment.

Retail pharmacists are overworked and already have the burden of excess work, long shifts, short to no breaks, and constant interruption. There is clearly a safety issue every time a pharmacist has to change focus from prescription checking to patient consultation, insurance claim support, staffing issues, health and beauty aid inquiries, and vaccination requests. Interruption is a primary cause of dispensing errors. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6499714/.

Although I no longer work in retail pharmacy, I would never return to an organization that provides vaccination of any kind. For example, providers were asked to monitor Covid-19 vaccine recipients for 15-30 minutes for signs of anaphylaxis. However, when I received my vaccine at Safeway, my interaction with the pharmacist lasted 30 seconds. The shot was administered, and she was off checking prescriptions, answering

phones, and ringing up customers. Any anaphylaxis would have gone unnoticed as I went about my shopping immediately after vaccination.

With children, immediate resuscitative care is crucial during anaphylaxis or other severe adverse reaction to medication. Pharmacists do not have the training to provide care during this situation, nor the time to monitor the many patients they may vaccinate.

As a parent, I am dismayed that the bill would allow a child to receive vaccination with a "caregiver" present and not a parent or legal guardian. The parent must manage the health and wellness of their child, and in no way should the state undermine that relationship. This bill is simply a back-door effort to allow childhood consent to vaccination as was allowed in SB378, to which I also am vehemently opposed (and ecstatic it was retracted).

In closing, please retract Senate Bill 372 immediately to promote parent's rights and the safety of our patients receiving pharmaceutical care.

Sincerely,

Peter D'Orazio, RPh

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OPPOSE SB372.pdf
Uploaded by: Ronit Zelivinski
Position: UNF

Dear Senator Augustine,

I strongly OPPOSE SB 372.

I am a Certified Nurse Midwife practicing in MD, DC and VA. I have personally been injured by a pharmacist administering the influenza vaccine to me in fall of 2016. During nursing school, I received the influenza vaccine at a local CVS in Montgomery County. The pharmacist hit a nerve in my deltoid muscle and I was in pain for six months. I could not properly move my arm for two years. For three months, I could not elevate my arm above eye level, nor lift anything heavier than 5 pounds. I still have limitations in movement and have not regained full range of motion despite intensive physical therapy and daily yoga.It was debilitating and affected all aspects of my life. Pharmacists are not trained nurses and 20 hours is NOT sufficient training to administer injections, particularly to children. Additionally:

- Vaccination is a medical procedure that must done by doctors who have patients medical records and know their patients the best.
- Pharmacists are not doctors, they MUST NOT have authority to order vaccines for children.
- Pharmacies are busy chaotic places; chaos calls for unexpected mistakes as it has already happened many times!
- Childhood vaccination MUST BE done by pediatricians.
- If vaccination is done at a pharmacy, pediatricians may not have complete records of their patience that may lead to inaccurate treatments and misdiagnoses.'

- This bill promotes very low standards by requiring only 20 hours of practical training.

Please **withdraw** SB 372.

Thank you,

Ronit Zelivinski

SB372_UNFAVORABLE_Cusack.pdf
Uploaded by: Sarah Cusack
Position: UNF

SB372: Health Occupations- Pharmacists- Administration of Vaccines
UNFAVORABLE
Sarah Cusack, MPT

Dear Chair Griffith, Vice Chair Klausmeier, and Distinguished Members of the Finance Committee,

As a pediatric physical therapist and a mother, I am opposed to the concept of this bill. Pharmacists are not pediatricians. Pediatricians are supposed to do a thorough assessment of a child before they recommend and administer any vaccination. The CDC recommended schedule it just that…. A recommendation! Pharmacists will just look at a child's age and give them everything on the list.

As a physical therapist, I do not look at a child's diagnosis, find a checklist in a textbook and start treating them according to a checklist. I do an assessment and come up with a treatment plan that is specific and individual to that child. That is what the pediatrician is supposed to do.

I have spoken to several young mothers who are hopeful that the bill will pass. They feel bullied in their appointments with the pediatrician and are asked to leave if they even ask a question about a shot that the child is about to receive. If the bill passes, they told me they will skip the pediatrician and get what shots they want, when they want them at the pharmacy. This will lead to a drop in vaccination rates in our state, and missed diagnoses and medical issues because pharmacists cannot examine the child.

I ask the committee for an Unfavorable report on SB372.

Thank You,
Sarah Cusack, MPT
District 14

UNFAV_SB372.pdf
Uploaded by: Shawna Sherrell
Position: UNF

SB372
UNFAV
Shawna Sherrell
District 5

Dear Senate Finance Committee,

I’m writing as a Maryland resident and as a parent asking that you give an unfavorable report for SB372: “Health Occupations - Pharmacists - Administration of Vaccines.”

Sincerely,

Shawna Sherrell

sb 372oppose note.pdf
Uploaded by: Sheila Jennifer
Position: UNF

Written Testimony Submitted to OPPOSE SB 372 February 27, 2023

Madam Chair, Members of the Senate Finance Committee,

In consideration of SB 372, "For the purpose of authorizing pharmacist to order and administer vaccinations" to minors, would the Finance Committee provide clarity to SB 372's provisions to:

1. Establish a timeline stated in Section 2 as "From July 1, 2021 to June 30, 2023 inclusive" Does this end the authorization for the bill?

2. The bill allows for the vaccination to be administered without a prescription. Therefore, "one effort to notify the minors primary care provider or other usual source of care" must be documented. This language seems to ignore Federal rule providing for a Vaccination Information Statement required to the parent/guardian. Define "other usual source of care" as stated. Again, is this language intentionally omitting parental/guardian notice of vaccination?

3. The bill states the "Act is an emergency measure, is necessary for the immediate preservation of the public health or safety." If EUA has been cancelled, to what emergency does this refer?
   IF the bill is from "July 1, 2021 to June 30, 2023, that leaves 5 months left to "preserve the public
   health or safety" ???

   As the members deliberate this bill, do any have reservations about the language in the bill allowing a pharmacist with 20 hours of training and a minimum of 2 hours of continuing education, ordering and administering a medical procedure such as a vaccination to minors between 3-ll years of age?

   SB 372 does not address an emergency. It creates one. Its claim of the need for immediate action for health or safety is unfounded and will no doubt lead to injury claims.
   Keep our children safe. OPPOSE SB 372.

   Sincerely,
   Sheila Jennifer
   Howard County, Maryland

Maryland against SB732 2023 Pharmacists bill Steve

Uploaded by: Steve Bress

Position: UNF

My name is Steve Bress. I have been a Maryland resident for much more than 50 years. I urge you to vote no on SB732. It is not in the best interests of Maryland residents. I wrote the following for the last time a bill such of this was presented a couple of years ago, and it applies virtually unchanged today. (A couple of items have had to be updated from the past, as Shoppers Food Warehouse has gotten out of the Pharmacy business.)

As to one of the specific problem areas of SB372, it has no mandatory language for informed consent, nor is there a requirement that a parent/guardian consent to the child's medical procedure. An adult caregiver, per the bill's wording, could be construed as a relative, therapist, doctor, or even a teacher. Possibly even a neighbor taking a bunch of kids on a field trip. All of these people would suddenly have the ability to make potentially dangerous medical decisions on behalf of the child. These caregivers cannot possibly be informed enough about the child's medical history or even current medical condition to be able to make such a decision. This is one of the reasons that medical decisions are safest when it is a decision made in discussion between the parents/guardians and the child's doctor(s).

Additionally, there is no section for mandatory VAERS reporting, with associated consequences for non-compliance, such as loss of license, in the tragic case where an injury occurs or may have occurred. If the Pharmacist is going to replace the doctor, they should also be responsible for reporting the injuries that they cause. After all, the point of this bill is to move these procedures out of the doctor's office, which would make the pharmacist the likely first point of contact. Unless the adverse reaction requires hospitalization, of course.

SB732 has as its basic premise that a Pharmacist should take the place of a highly trained and experience medical professional when it comes to administering vaccines, and the local pharmacy is an appropriate venue for such administration. I must, therefore, assume that the sponsors have never actually set foot in a commercial pharmacy, such as CVS, or a pharmacy within a grocery store, such as might be found in a Giant Foods.

Given that, I would be pleased to share my experiences with both types of pharmacies. I won't be naming names, but my experiences have been similar amongst a wide variety of retail pharmacy locations.

- The Pharmacist gave me a prescription that required refrigeration. It was in the massive pile of other prescriptions and nowhere near the fridge. I was asked if I wanted it anyway. I suggested that I felt more comfortable with a properly maintained prescription. In the case of this particular prescription, it would simply have been ineffective. If a vaccine had been cared for in this manner, it could be deadly.
- I had to intervene in a dispute between a patient and the pharmacist. She was berating and threatening the staff. For some reason, they were unable or unwilling to have the

woman removed. Had I allowed her to continue to harass my pharmacists, I would not have expected to get the right medication. I certainly would not have wanted one of them to give me a vaccine at that time, given the high levels of agitation that she caused.

- Pharmacies have no ability to understand medically complex individuals. No matter how many times I explain allergies to the inactive ingredients in the drugs, they still will make a substitution, often without informing me, with a drug to which one of my family members is allergic.
- On that topic, since pharmacists cannot track and do not care about allergies, they certainly cannot be trusted to inquire, understand, and act on allergy information provided by a potential patient. Which assumes that the patient, who may be a minor under this bill, is capable of understanding that it is their responsibility to inform the pharmacist about allergies and other embarrassing personal information. The patient's doctor, of course, should already know and take proper precautions.
- Bounties for medical procedures are unacceptable, but they are commonplace at pharmacies. False advertising is rampant as well. The shots aren't "free" unless the pharmaceutical companies have all suddenly gotten very generous. (While there is usually an asterisk that says the pharmacist will explain how it is free, it is still not free.)
- I have witnessed many, many vaccinations given at local pharmacies and given the small amount of square footage allocated to the medical procedure section, I have heard the interaction between the pharmacist and the patient. I have NEVER, not once, as in it hasn't happened, heard the pharmacist give the patient the information that would allow for informed consent.
- Speaking of lack of space, I have never seen a bed for a patient to lie down upon for when he or she is about to pass out after vaccination. This would be uncomfortable and dangerous.
- On that topic, drive through vaccinations sound like a great idea until someone passes out while driving.
- One pharmacist substituted a generic drug for a name brand drug, for which I paid a significant amount of money. It did not do its job. When I found out what had happened and talked to the pharmacist, he would not check inventory to prove my claim. Later on, after a change in management, I found out that I wasn't the only one. There is no reason to believe that this wouldn't happen with vaccines. A saline solution is far cheaper than the actual vaccine. Should a patient get sick, it would just be assumed to be a simple vaccine failure.

There is no such thing as a 100% safe medical procedure. No matter how often the phrase "safe and effective is repeated," it does not suddenly become true. Without a parental consent

requirement for medical procedures, a minor has no advocate that understands the details of the minor's health and the risks posed by the procedure. Contests, bounties and other forms of manipulation are not reasonable when it comes to invasive medical procedures. What is reasonable is informed consent along with doctor and parental involvement. I urge you to vote against this bill that weakens parental rights and endangers children.

Steve Bress

Germantown, MD

SB372.pdf
Uploaded by: Theresa Myers
Position: UNF

February 27, 2023

Maryland Senate
Finance Committee

Ref: SB372-Pharmacists- Administration of Vaccines

Dear Finance Committee,

I am asking you to vote UNFAVORABLE for SB372. Pharmacists do not have the medical history of the patient. How do they know what they are allergic to? What happens if they have an allergic reaction while at the pharmacist? Who liable if something goes wrong? This bill is unnecessary and should not go through.

Please vote UNFAVORABLE for SB372.

Sincerely,

Theresa Myers

SB0372_Tom and Tina Wilson_Unfavorable.pdf
Uploaded by: Thomas Wilson
Position: UNF

Written Testimony of Thomas P. and Tina M. Wilson

RE: In Opposition to Senate Bill SB0372 - Health Occupations - Pharmacists - Administration of Vaccines

February 27, 2023

As citizens of the state of Maryland, we oppose Maryland **Senate Bill SB0372** as currently drafted**.** This testimony seeks to express our concerns around **SB0372.**

This bill is another attempt at Government over-reach, usurping parental rights and control over their children without articulating any specific benefits. The Government and the Government agencies such as the NIH and CDC have the funding and influence to try to convince parents to vaccinate their children, although the integrity of these organizations has been questioned based on their close connections with and funding provided by the pharmaceutical industry. In the final analysis, it is the parents that should make the decision and have control. The drafted bill does not appear to target any specific vaccinations but opens the door to any and all vaccinations now or in the future. While there may be some rationale for pharmacists having the ability to administer vaccinations, it should never be without parental consent, and never for minor children as this bill suggests.

We believe it's also dangerous to assume that minors have all the mental capacity to fully understand the implications of the vaccination decisions to achieve "informed consent". It's probable that minors would view doctors and/or pharmacists as having positions of authority that could inadvertently or directly coerce their decision. We have had personal experience with doctors who directly pressure and coerce children for particular treatments or medications and have resisted those attempts to the long-term benefit of our children.

The experience during the COVID pandemic appears to be lost on the sponsors of this bill - "one size fits all" policy of vaccine mandates added little of no value to persons under 20 years of age. In fact, the peer reviewed literature on the efficacy and side effects of the covid-19 vaccine shows clearly that for those 20 years of age and younger, the risk of harm or death from the vaccine is far greater than the benefit, especially if the infected individual is treated promptly. It is imperative that parents determine whether a child receive any vaccine. As a parent who is well acquainted with the facts, I should have the right to determine how to best safeguard my child...and so should every parent.

We oppose SB0372 and ask the committee to oppose it as well. Thank you for your consideration.

OPPOSE SB 0372.pdf
Uploaded by: Vicki Zelivinski
Position: UNF

I know that my daughter Ronit Zelivinski has shared her experience with you about an injury from the influenza vaccine. My daughter received this vaccine due to her nursing school requirements in 2016. Her vaccine was administered by a local CVS pharmacist, and we went to multiple neurologist's visits because of the immobility of her arm. Afterwards, she received a letter that no vaccine should ever be administered to her without consulting a neurologist first. This clearly shows that pharmacists who are inexperienced may cause harm.
My daughter's arm has still not regained full mobility.
I am strongly opposing to the additions to SB 372 that will allow pharmacists with 20 hours of training to administer vaccines,
especially to children. Childhood vaccinations should be done by pediatricians that have received sufficient training, know their patients, and can provide necessary treatment in case of possible complications.

Please consider all possible complications that could happen, as well as the consequences of these complications, and withdraw the latest additions to SB 372.

With respect,
Vicki Zelivinski
Montgomery County resident for 26 years.

oppose sb372.pdf
Uploaded by: Victoria Millsaps
Position: UNF

Opposition to SB372

Tori M <tbyrd14@hotmail.com>

Mon 2/27/2023 2:22 PM

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Oppose SB372

Hello Finance committee members,

In todays episode of soccer moms saving our kids from overreaching tyrannical measures: ....😳....

This bill will do more harm than good.

SB372-"That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety,..."

There is no emergency. There will undoubtedly be other scenarios that seem to coincidentally create more "emergencies" and this bill makes it far more possible for incorrect injections to be given, improper techniques performed, and even more situations where uninformed consent take place.

No parent/adult could possibly know the contraindications of all shots that could be given by a pharmacist and no pharmacist will know the full medical history of their customer.

One of many examples: DOCTORS this past year were prescribing Paxlovid under an EUA without considering the extremely long list of medicines it can counter act with. This caused many to have horrible side effects and adverse reactions that could have been avoided. I believe it was done under pressure and blind trust in the FDA.
This is by doctors WITH medical history and knowledge of current meds at their fingertips.

There is no evidence that expanding the access to vaccines to these younger age groups improves health outcomes. It can virtually do the exact opposite.

Thank you for your time and attention,

Victoria Millsaps
Calvert County MD